Volume IV 2010

# CHINA MEDICAL DEVICE NEWSLETTER

中国医药国际交流中心

Johnson & Johnson MEDICAL
强生（上海）医疗器材有限公司

## NEWS

### SFDA Convenes National Meeting on Food and Drug Supervision

The State Food and Drug Administration held a meeting on food and drug supervision from August 1 to 3, 2010 in Zhejiang Province. There was in-depth concept of supervision. The priorities in the reform and development of food and drug supervision were studied. Shao Mingli, Commissioner of the State Food and Drug Administration, summed up what the SFDA had done in the first half of the year and made arrangements and deployed the work for the second half of the year. Deputy Commissioner Wu Zhen made arrangements for E-Supervision of essential drugs for the second half of the year. Deputy Commissioner Bian Zhenjia made arrangements for the safety of food in the catering service, regulation of health food, cosmetics and medical devices and inspection of drugs for the second half of the year.

In view of next half year's supervision and management work schedule, Deputy Commissioner Bian Zhenjia stressed that active coordination with relative departments of State Council is necessary to speed up the revision of Regulations on Supervision and Management of Medical Device, to reinforce the rectification and regulation of high-risk medical devices and to severely punish offenders using illegal marketing strategies. (August 3, 2010)

### SFDA Deputy Commissioner Bian Zhenjia delivers a speech at the opening ceremony of the China International Medical Device Regulatory Forum 2010

From 7th to 10th September China Center for Pharmaceutical International Exchange hosted the China International Medical Device Regulatory Forum 2010 on Supervision and Administration for Medical Device to promote domestic and international exchange on laws and regulations about medical devices and to act in alignment with drawing and revising of Regulations on Supervision and Management of Medical Device and supporting regulations. SFDA Deputy Commissioner Bian Zhenjia attended the opening ceremony. His speech was on the necessity to implement systematic rules and regulations to supervise and manage Chinese manufactured medical devices, reinforce international exchange and carry out a scientific style of supervision and administration.

(September 10, 2010)

### SFDA Deputy Commissioner Bian Zhenjia heads the team for special inspection on Medical Molecular Sieve Oxygen Generator in Zhejiang Province

SFDA Deputy Commissioner Bian Zhenjia led an inspection team during the period between July 29 to July 30 to conduct special inspection on molecular sieve medical oxygen generator at medical institutions in Zhejiang Province. Bian Zhenjia mentioned the following; 1. Welcome the provincial FDA of Zhejiang to put forward ideas and suggestions for the revision of relative standards for molecular sieve medical oxygen generator as revised by SFDA; 2. Study with care and define the scope of application of molecular sieve medical oxygen generator; 3. Actively explore management models for molecular sieve medical oxygen generator. (August 5, 2010)

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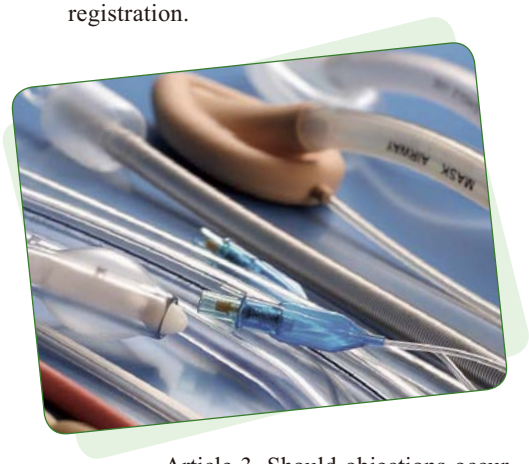
# Notification on the Issuance of the *Reevaluation Procedures for Medical Device Registration (trial Version)*

To strengthen the administrative evaluation and approval for the reevaluation of medical devices registration, SFDA issued *Revaluation Procedures for Medical Device Registration (Trial Version)* on August 26.. Following is the full text:

Article 1. To strengthen the administrative evaluation and approval for the reevaluation of medical devices registration,, secure opening, fairness and justice of reevaluation; improve the efficiency of registration and reevaluation hereby setting these procedures.

Article 2. These procedures apply to both domestic and imported medical devices (including in vitro diagnostic reagents) on Initial registration, re-registration and reevaluation application for rejection of changing application of registration certificate or decision of rejecting registration.



Article 3. Should objections occur with regard to decisions of rejection or disapproval of registration, the applicant can submit reevaluation applications to decision-making FDA departments within twenty (20) working days after official notice is received.

The contents of reevaluation applications are confined to the original application items and documents.

Article 4. The following documents are required for the applicant to tender a reevaluation application:

1) *Application Form for Reevaluation of Medical Devices Registration* (Attachment 1) Signed by production enterprises or its agent.

2) Photocopy of the original evaluation decision notice.

For application of reevaluation of imported medical devices registration, if the reevaluation application is submitted by agent, the agent must be the one of the original registration application project.

Article 5. After the Document of the local Food and Drug Adiministration accepted reevaluation application, the reevaluation shall be carried on according to the procedure of original registration evaluation.

Registration reevaluation time limit for domestic Class 1 medical devices is fifteen (15) working days; thirty (30) working days for domestic Class 2 medical devices and forty five (45) working days for domestic Class 3 and imported medical devices. The time limit of reevaluation for modification of registration certificate is twenty (20) working days.

Article 6. After reevaluation, if local Food and Drug Adiministration decide to maintain the original evaluation conclusion, a Notice of Reevaluation Decision for Medical Devices Registration(Attachment 2) shall be issued.

If the decision is made to rectify the original evaluation conclusion, the related document shall be issued directly.

Article 7. Permission for a reevaluation decision will be forwarded to the applicant within ten (10) working days after the local Food and Drug Adiministration agree with reevaluation.

Article 8.The local Food and Drug

# 国家食品药品监督管理局印发《医疗器械注册复审程序（试行）》的通知

为加强医疗器械注册复审的审评审批工作，国家食品药品监督管理局8月26日印发了组织制定的《医疗器械注册复审程序（试行）》。全文如下：

第一条　为加强医疗器械注册复审的审评审批工作，保证复审工作的公开、公平、公正，提高复审工作效率，制定本程序。

第二条　本程序适用于境内、进口医疗器械（含体外诊断试剂）首次注册、重新注册、注册证书变更的退审或不予注册（含不予变更）审批决定的复审申请。

第三条　申请人对食品药品监督管理部门作出的退审或不予注册决定有异议的，可以在收到审批决定通知之日起20个工作日内，向做出审批决定的食品药品监督管理部门提出复审申请。

复审申请的内容仅限于原申请事项和原申报资料。

第四条　申请人提出复审申请应当提交以下资料：

（一）由生产企业或其代理人签章的《医疗器械注册复审申请表》（附件1）；

（二）原审批决定通知的复印件。

对于境外医疗器械注册复审申请，如复审申请由代理人提出，该代理人应是原注册申报项目的代理人。

第五条　食品药品监督管理部门受理复审申请后，应当按照原注册审评审批程序，对复审项目进行复审。

境内第一类医疗器械注册复审时限为15个工作日；境内第二类医疗器械注册复审时限为30个工作日；境内第三类、境外医疗器械注册复审时限为45个工作日；医疗器械注册证书变更复审时限为20个工作日。

第六条　经复审，食品药品监督管理部门决定维持原审批结论的，应当核发《医疗器械注册复审决定通知》（附件2）；决定对原审批结论予以纠正的，应当直接核发相关许可文件。

第七条　食品药品监督管理部门应当自作出复审决定之日起10个工作日内核发、送达复审决定。

第八条　已作出复审决定的，食品药品监督管理部门不再受理申请人再次提出的复审申请。

Adiministration will not accept reevaluation application again if reevaluation decision has already been made.

Article 9. The local Food and Drug Adiministration will not accept reevaluation application if the applicant lodges objections pertaining to decisions that resulted in initial disapproval and rejection of registration or having applied for administrative reconsideration or litigation.

Article 10. These procedures come into full effect as of the date of issuance.

(August 26, 2010)

第九条　申请人对食品药品监督管理部门作出的退审或不予注册的决定有异议，且已申请行政复议或者提起行政诉讼的，食品药品监督管理部门不受理其复审申请。

第十条　本程序自发布之日起施行。

（2010年8月26日）

## Regulations on *Supervision and Management of Medical Device (Revised Draft)* soliciting opinions from the general public

To further improve the transparency and quality of legislation the Legal Affairs Office of the State Council has decided to publicize the full text of Regulations on Supervision and Management of Medical Device (Revised Draft) soliciting opinions from the general public to facilitate research and revise this document. The revised version will be submitted the Standing Working Conference of the State Council for deliberation and approval.

Regulations on the Supervision and Management of Medical Device (Revised Draft) stipulates that the State conducts a categorized management for medical devices according to anticipated purpose, structural features, ways and usage of application taking into considering potential risks to the human body.

Medical instruments are classified into three distinct categories.

Class 1. Medical devices that are low risk.

Class 2. Medical devices have intermediary risks.

Class 3. Medical devices that are high risk. For example:--medical devices for implantation, or support and sustenance of life.

Class 1 medical devices shall be implemented with Records Management. Class 2 and Class 3 Medical devices shall be implemented with Registration Management. The State will establish "'Product Recall System". Once the defective or rejected medical devices are identified and confirmed in the specific class category the devices must be immediately recalled by manufacturing enterprises. And Unhealthy Events Monitoring System shall also be established to collect, analise and evaluate the unhealthy events about medical devices.

(September 6, 2010)

## 《医疗器械监督管理条例(修订草案)》公开征求意见

为了进一步增强立法的透明度，提高立法质量，国务院法制办公室决定向社会各界征求对《医疗器械监督管理条例（修订草案）》的意见，以便进一步研究、修改后报请国务院常务会议审议。

《医疗器械监督管理条例（修订草案）》征求意见稿规定，国家对医疗器械实行分类管理，根据其预期目的、结构特征、使用方式、使用状态等可能对人体产生的风险，将医疗器械分为三类：风险程度较低的为第一类医疗器械；风险程度高的为第三类医疗器械，如植入人体或者用于支持、维持生命的医疗器械等；风险程度界于第一类和第三类医疗器械之间的为第二类医疗器械。第一类医疗器械实行备案管理，第二类、第三类医疗器械实行注册管理;国家将建立医疗器械产品召回制度,生产企业发现医疗器械不符合相关要求的,应立即召回;建立医疗器械不良事件监测制度,收集、分析、评价、控制医疗器械不良事件。

（2010年9月6日）

# Q&A
# 问答栏目

## Q&A on Clinical Materials Relating to the Guiding Principles on the Technical Review for the Registration of Medical X-ray Diagnostic Equipment (Category III)

(To continue)

**Q: What do you need to considerer during clinical trial?**

**A:** (1) The purpose of clinical trial is to evaluate the medical device to see if it can meet the anticipated safety assumption and expected medical effect (value) in normal operating conditions.

## 关于医用X射线诊断设备（第三类）产品注册技术审查指导原则中临床试验的问题解答

（接上期）

问：进行临床试验应考虑什么问题？

答：（1）临床试验的目的在于评价该医疗器械在正常使用条件下是否符合预期

(2) Clinical test should be provided with specially designed clinical trial scheme (including test purpose, test method, selection of subject, evaluation indicators and evaluation method of curative effect/safety, risk control, potential harm or risk analysis, starting and ending time of test, data management and statistics analytic method, etc.). The design of clinical trial scheme should be jointly completed by manufacturer, clinical experts, and statisticians. Statistics analytic staff should participate in the whole course of clinical trial (including scheme design, data management, statistical analysis, and statistical analysis report).

(3) Clinical evaluation indicators

Primary evaluation indicators: coincidence rate of the clinical diagnose requirements in image quality; secondary evaluation indicators: service convenience of equipment, functions of equipment and stability satisfaction.

(4) Clinical evaluation criteria

See Appendix V.

(5) Number of cases for clinical trial at each position

The single-group test of the target value method could be adopted clinical trial.

According to clinical requirements, the required coincidence rate of the clinical diagnose requirements in image quality should not be lower than 85% (target value). Supposed that the required coincidence rate is 95%, the minimum number of subjects for the trial should be 80 cases when the levels of significance at both sides are 0.05 and the power of test is 80%.

80 cases for chest, in which, at least 10 cases include the projection at lateral and frontal positions.

Bone and soft tissue should include three positions (head, lumbar, and pelvis/hip joint). One case for any projection position of head; lumbar must have lateral and frontal projection and only one case; and one case for the frontal position of pelvis/hip joint, totally 80 cases; each position should have at least 10 cases.

Gastrointestinal series include four positions: esophagus, stomach, intestinum tenue, and barium enema (full gastrointestinal contrast may be counted as 3 cases), as a total of 80 cases; each position should have at least 10 cases.

DSA should include four positions: abdominal aorta, hepatic artery, renal artery, and common iliac artery, as a total of 80 cases; each position should have at least 10 cases.

The clinical trial cases at each position should meet statistical principles (without prejudice to the ethic principles, the same subject may be used for the validation of many positions).

(6) Evaluation on clinical trial effects

a. Image definition evaluation shall adopt the way of double-blinded evaluation (i.e., evaluate the quality of clinical image with back-to-back method); when conditions permit, it is recommended to adopt the method of third-party evaluation who does not participate in the clinical trial. The requirements are:

- The image quality of subject should at least be 95% of the required coincidence ratey with clinical diagnosis (i.e., among 100 persons, at least the image quality of 95 persons should meet the requirements);
- The image quality of subject determined as “invisible” should not exceed 2% (i.e., among 100

安全性设想和预期医疗效果（价值）。

（2）临床试验应有专门设计的临床试验方案（包括：试验目的，试验方法，受试者的选择，疗效/安全性评价指标及评价方法、危险性控制，潜在的伤害或风险分析，试验起止时间、数据管理及统计分析方法等）。临床试验方案的设计应由厂家、临床专家和统计学家共同完成。统计分析人员应全程参与临床试验（包括：方案设计、数据管理、统计分析及统计分析报告）。

（3）临床评价指标

主要评价指标：影像质量的临床诊断要求符合率；次要评价指标：机器使用便捷性、整机功能及稳定性满意度。

（4）临床评价标准

见附录V

（5）每一部位的临床试验例数

临床试验可采用目标值法的单组试验。

根据临床要求，影像质量的临床诊断要求符合率不得低于85%（目标值），假设试验组影像质量的临床诊断要求符合率为95%，则当双侧显著性水平取0.05、检验效能为80%时，试验最少需要的受试者数为80例。

胸部80例，其中至少有10例含正侧位投照。

骨与软组织部位包含三个位置（头、腰椎、骨盆/髋关节），头任何投照体位计1例；腰椎必须进行正侧位投照且计为1例、骨盆/髋关节正位计1例，合计80例；每位置最少病例数10例。

胃肠造影包含四个位置：食道、胃、小肠、钡灌肠（全消化道造影可计3例），合计80例；每位置最少病例数10例。

DSA包含四个位置：腹主动脉、肝动脉、肾动脉、髂总动脉，合计80例；每位置最少病例数10例。

每一部位的临床试验例数均需符合统计学原则（在符合伦理学的原则下，同一个受试者可以用于多个部位的验证）。

（6）临床试验效果评价：

a. 图像清晰度评价采用双人盲态评价的方式（即：双人背靠背评价临床影像的质量），有条件时建议采用由不参与临床试验的第三方进行评价的方法。要求：

- 受试者的影像质量达到“临床诊断要求符合率”至少为95%（即：100个人中，至少有95个人的影像质量评估为符合要求）；
- 受试者影像质量为“不可见”的比

persons, the image quality of at least 2 persons is evaluated as “invisible”);

b. the satisfaction rate of equipment service convenience, functions of complete machine and stability should meet 85%; the rate of basic satisfaction and above average level should be 95%.

(7) Clinical trial report and statistics analytic report

According to the statistics analytic report, the leading unit shall issue the clinical trial report on a certain indication. Statistics analytic report should consolidate the data of the same indication (position) in all centers into one for statistical analysis and a general statistics analytic report should be issued for each position.

Data management should be conducted for all subjects selected. In case of any indistinct problems, should be verified with original record. Statistical analysis should at least include the following four parts:

a. description on completion of clinical trial: including the summary of clinical trial (screening number of people, selected number of people, completed number of people, loss of visit/withdrawal/eliminated number of people, etc.);

b. baseline description: describe baseline demographic indicators of all selected subjects (ITT analytic set) and the indicator of other related disease histories;

c. curative effect/effect evaluation: conduct statistical analysis on all selected subjects (ITT analytic set) and the subjects finally completed (PP analytic set) respectively. During curative effect analysis, besides point estimation, the creditability interval for 95% of the point estimation should be provided;

d. during safety evaluation, all selected subjects should be analyzed (SS analytic set) without omission of any adverse event (including laboratory indicators: normal condition before the test, abnormal condition after the test, and the event with clinical meaning). For all adverse events, the relevance with the product under study should be evaluated.

(8) The entire course of clinical trial should be under strict supervision and quality control. All test records must be complete, authentic, clear, and objective. Subjects should be selected continuously during test. (July 1, 2010)

例不得超过2%（即：100个人中，最多有2个人的影像质量评估为“不可见”）；

b. 机器使用便捷性、整机功能及稳定性满意度达到85%，满意及一般达到95%

（7）临床试验报告及统计分析报告

由组长单位根据统计分析报告，出具某一适应症的临床试验报告。统计分析报告应将所有中心的同一适应症（部位）的数据合并在一起进行统计分析，并对每一部位出具总的统计分析报告。

应对所有入选的受试者进行数据管理，遇有不清楚的问题时，应与原始记录核对。统计分析应至少包括如下四部分：a、临床试验完成情况描述：包括临床试验概况（筛选人数、入选人数、完成人数、失访/退出/剔除人数等）；b、基线描述：应对所有入选受试者（ITT分析集）的基线人口统计学指标及其他相关病史指标等进行描述；c、疗效/效果评价：应对所有入选的受试者（ITT分析集）和最终完成试验的受试者（PP分析集）分别进行统计分析。疗效分析时，除点估计外，还应给出点估计的95%的可信区间；d、安全性评价时，应对所有入选的受试者进行分析（SS分析集），不能遗漏所有发生的任何不良事件（包括实验室指标：试验前正常、试验后异常并有临床意义的事件），对所有发生的不良事件应评价其是否与所研究产品有关。

（8）临床试验的整个过程要有严格的监督和质量控制，所有试验记录均要完整、真实、清晰、客观。应在试验期间内连续入选受试者。（2010年7月1日）

## Meeting Brief

**Grand opening in Beijing of the China International Medical Device Regulatory Forum 2010**

From 7th to 10th September, the China International Medical Device Regulatory Forum 2010 sponsored by China Center for Pharmaceutical International Exchange was held at Jiu Hua Shan Zhuang in Beijing .

This forum converged over 700 participants, including leaders and distinguished guests from medical devices administration departments in China and abroad, The participants also included experts affiliated with medical devices technical institutions, medical devices testing institutions and production enterprises.

SFDA Deputy Commissioner Bian Zhenjia attended the forum giving an important speech. The relevant SFDA staffs also delivered speeches in related issues such as "China Regulations of Medical Devices Registration", "China Regulations

## 会议简讯

**2010年医疗器械监督管理国际论坛在京隆重召开**

9月7～10日，中国医药国际交流中心举办的“医疗器械监督管理国际论坛”在北京九华山庄开幕，来自国内各地和国外医疗器械监管部门的领导和贵宾，医疗器械技术机构、检测所、相关领域专家以及医疗器械生产企业的700多人参加了本次论坛。

国家食品药品监督管理局边振甲副局长出席论坛并发表了重要讲话。国家食品药品监督管理局有关人员就“中国医疗器械注册制度”、“中国医疗器械标准制度”、“医疗器械不良事件监测与医疗器械检

of Medical Devices Standards", "Supervision on Unhealthy Event and Testing of Medical Devices", "Technical Evaluation Procedure for Medical Devices and Application of Guiding Principles of Technical Evaluation. Speakers from America, EU and other countries also made excellent speeches, viz; "EU Laws and Regulations on Medical Devices and the International Development Tendency", "Perspectives on the Coordination of Global Laws and Regulations on Medical Devices", "Pre-market Requirements for Medical Devices in Austria", "Status of Japan's Laws and Regulations on Medical Devices", "The Role of Clinical Evidence for Premarket Approval of Medical Devices", "Incessant Evolution of Directives for Medical Devices in Europe— Past and Future."

Wang Baoting, Director of Department of Medical Devices of SFDA voiced a closing ceremony speech on the topic "The Coordination of Laws and Regulations Concerning Medical Instruments in Asia.".

Six Professional sub-forums were held concurrently within the main forum session:

1. Forum on medical devices for imaging; 2. Forum on medical devices for cardio-cerebral system and medical macromolecule products and consumables; 3. Forum on orthopedic and surgical devices; 4. Forum on ophthalmological optics instruments; 5. Forum on medical devices in vitro diagnosis (IVD); 6. Forum on pharmaceutical combination products and dental equipment.

Comprehensive, in-depth coverage, lively interaction between guests and audience attending the forum was favorably acknowledged by all the participants.

(September 13, 2010)

测”、“医疗器械技术审评程序及技术审评指导原则的应用”等内容进行了精彩的发言；来自美国、欧盟等国家的演讲者就“欧盟医疗器械法规和国际发展趋势”、“全球法规协调的展望”、“澳大利亚医疗器械的上市要求”、“日本医疗器械法规的现状”、“临床证据在上市前审查中的作用”、“欧洲医疗器械指令的持续变革——过去与未来”等内容进行了发言。

国家食品药品监督管理局医疗器械监管司王宝亭司长在主论坛上就亚洲医疗器械法规协调组织的工作做了介绍，并在闭幕式上致辞。

论坛期间同时进行的6个专业分论坛为：医用影像类器械论坛；心脑系统器械、医用高分子产品及耗材论坛；骨科及手术器械论坛；眼科及视光学器械论坛；体外诊断器械论坛；药械组合产品、齿科器械论坛。

论坛内容丰富、覆盖面广、嘉宾与听众参加踊跃，得到了与会者的好评。

（2010年9月13日）

## SPECIAL FOCUS 业界专题

# Summary of Medical Device Administration in USA (III)

# 美国医疗器械管理概况（三）

**2**. Medical Device Pre-marketing Management and Supervision

Medical devices vary widely in their complexity and their degree of risks or benefits. They do not all need the same degree of regulation. Thus, FDA divided all medical devices into three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the devices.

According to the recommendation of advisory committee, FDA will announce the final classification in the Federal Register. The classes of most devices can be found on Section 862 to 892 in Volume 21 of the Code of Federal Regulations (CFR). There are approximately 1,700 devices within 16 medical categories. Of the 1,700 classified devices, 45% are Class I, 47% are Class II and 8% are Class III.

Class I - Genaral Control: Class I devices are subject to the general regulatory control. They present minimal potential for harm to the user and are often simpler in design than Class II or Class III devices, such as thermometers, examination gloves and elastic bandages. General control includes: prohibition of selling adulterated and misbranded devices; manufacturing devices in accordance with the Quality Systems regulations and GMP; labeling devices in accordance with labeling regulations; using FDA Form 2891 for registration; and submission of a pre-market notification 510(k) before marketing a device. Most Class I devices are exempt from the pre-market notification and/or the Quality

2. 医疗器械上市前监管

医疗器械的复杂性和风险或受益程度变化很大，不需要同一尺度的监管。因此，FDA根据管理需要的水平把所有医疗器械分成3个监管类别，从而保证器械的安全性和有效性。

根据分类委员会的建议，FDA将在《联邦注册簿》（Federal Register）上公布最终的医疗器械分类。绝大多数器械的类别能在《联邦法规典集》(Code of Federal Regulations[CFR])第21卷第862至892篇分类规则中找到。在16个医学大类中有大约1700种器械的分类，其中45%是第一类，47%是第二类，8%是第三类。

第一类—— 一般控制：第一类器械采用一般的监管控制。它们具有对使用者最小的潜在危害和比第二、三类器械更为简单的设计，例如体温计、医用手套和弹性绷带等。一般控制包括：禁止伪劣和标记不当的器械出售；器械制造要遵守质量体系规范和GMP；器械标记要遵守标签规范；使用FDA2891表建立登

System regulations. In general, the devices can be marketed after submitting FDA Form 2891.

Class II - Special Control: Class II devices are those for which general control alone is insufficient to assure safety and effectiveness, and existing methods are available to provide such assurances, for example, ECGs, powered wheelchairs and ventilators. In addition to complying with general control, Class II devices are also subject to special control to assure safety and effectiveness. Special control may include special labeling requirements, mandatory and voluntary performance standards and post-marketing supervision. FDA requires pre-market notification 510(k) for such devices, and manufacturers must submit the 510(k) to FDA at least 90 days before marketing. After the 510 (k) is reviewed, the device can be sold in the market.

Class III - Pre-market Approval: Class III devices are usually those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which potentially present an unreasonable risk of illness or injury. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through general or special controls, such as cardiac pacemakers, artificial hearts and artificial blood vessels. Pre-market approval (PMA) is the required process of scientific review to ensure the safety and effectiveness of Class III devices. The manufacturer must submit to FDA a PMA application and other relevant information, including well-controlled clinical data, safety and effectiveness reports, and other related information. Within 45 days after a PMA is received by FDA, the applicant sall be notified whether the application has been filed. The decision of approvable or not approvable will be made within 180 days.

In addition to medical device classification management, the other important regulations for pre-marketing supervision also include Good Manufacturing Practice (GMP).

Clinical study: A clinical study report may be required in nearly 10% in support of pre-market notification [510(k)] submissions and in most cases in support of a pre-market approval (PMA) application. All clinical studies performed in support of a 510(k) or PMA must be conducted in accordance with the Investigational Device Exemption (IDE) regulation. This requires the manufacturer to obtain FDA approval of the study before it starts, to ask for detailed opinion from each patient, and to arrange proper monitoring during the conduct of the study. In the clinical study period, FDA has the right to inspect and audit the clinical research unit and its implementation of plans to ensure their compliance with the IDE regulation.

Good Manufacturing Practice (GMP): The current Good Manufacturing Practice (GMP) requirements set forth in the Quality System (QS) regulation are promulgated under section 520 of the Federal Food, Drug and Cosmetic (FFD&C) Act. The 1997 revised GMP requirements are much closer to ISO 9001. This regulation covers quality management and organization, device design, buildings, equipment, purchase and handling of components, production and process controls, packaging and labeling controls, device evaluation, distribution, installation, complaint handling, servicing, and records. It requires that all manufacturers shall have a quality system for the design and production of medical devices.

记：以及器械上市前报送上市前通知510(k)。但是大多数的第一类器械都豁免上市前通知和/或质量体系规范。一般来说，填交FDA2891表后，器械就可以上市了。

第二类——特殊控制：第二类器械是指那些仅一般控制不足以确保其安全性和有效性，同时对使用者具有某种潜在的危害且现有的方法可以提供足够的保证的医疗器械，譬如心电图仪、电动轮椅和呼吸器等。除了遵守一般控制要求外，第二类器械也要服从特殊控制以保证其安全性和有效性。特殊控制包括：特殊标签要求，强制的和自愿的性能标准，以及上市后的监督。FDA对这类器械通常要求上市前通知510(k)，制造商必须在上市前90天提出申请。通过510(k)审查后，器械才可以在市场上销售。

第三类——上市前批准：第三类器械通常是指那些支持或维持人体生命的和预防损害人类健康的或阻止疾病与伤害的，潜在、不合理风险的，但是仅靠一般或特殊控制不足以保证其安全性和有效性的医疗器械，例如心脏起搏器、人工心脏和人工血管等。上市前批准(PMA)是确保第三类器械安全性和有效性而进行科学审查的必备程序。制造商在上市前必须向FDA递交PMA申请书及其他相关资料，包括控制良好的临床研究，有关安全性和有效性的完整报告，以及与器械制造相关的资料。FDA在收到PMA申请后45天内通知制造商是否立案审查，并在180天内做出是否批准的决定。

除了医疗器械分类管理外，器械上市前监管的其他重要的规范还包括临床研究和良好制造规范(GMP)。

临床研究：有近10%在报送510(k)和绝大多数在申请PMA时，都要求提交临床研究报告。所有支持510(k)和PMA的临床研究必须在遵守研究用器械豁免(IDE)规范下进行。要求制造商在临床研究启动之前要获得FDA的批准，征求每个患者详尽的意见和进行研究全过程的适当监控。在临床研究期间，FDA有权检查和审计临床研究单位及其计划实施情况，以确保符合IDE规范。

良好制造规范(GMP)：现行的GMP在质量体系(QS)规范中被提出，发布在《联邦食品、药品和化妆品法》第520节中。1997年修订后的GMP要求与国际标准化组织(ISO)的9001标准更加接近。该规范覆盖了质量管理和组织、器械设计、厂房、设备、采购和原材料处理、生产和加工控制、包装和标签控制、器械评价、分发和装配、抱怨处理、服务以及记录。每一个制造商都要求建立一套医疗器械设计和生产的质量体系。

# Import and Export of China's Medical Device in the first half of 2010

According to statistics released by the China Chamber of Commerce of Medicine & Health Products Importers & Exporters the total volume of import & export of China's medical devices in the first half of 2010 amounted to 10,088 million US dollars, a 27.50% increase on equal terms. Export volume amounted to 6,573 million US dollars, a 26.86% increase on equal terms and import volume amounted to 3,515 million dollars, a 28.15% increase on equal terms.

In the first half of 2010 a total of 17,600 enterprises engaged in 99 types of medical devices exporting their products to 215 countries and regions. Among the top-10 exporters, 7 are foreign-owned enterprises or joint ventures.

Asia, Europe and North America remain to be major export destination markets of China for the first half of 2010 with a corresponding export volume;- 2,164, 1,838, and 1,878 million dollars respectively amounting for 89.45% of total export. America, Japan and Germany are still the top 3 export markets of China's medical devices which accounts for 44.03% of total export.

In the first half of 2010, China imported medical devices from 93 countries and regions. Europe has the major share with of 38.59% of total import. European countries like Germany, Switzerland, Ireland, Holland and Britain constitute 6 of the top 10 trading partners of China's importation of medical devices.

In the first half of 2010, China had a total of 7,790 enterprises engaged in the import of medical devices. Among the 9 products with the import volume up to 100 million U.S. dollars each, .the top three categories are: 1. X-ray application equipment for medical treatment surgical or veterinary purposes; 2. Medical equipment or apparel for physiological defects or implanted instruments; 3. Medical apparatus and instruments for other medical treatments, or for surgical or veterinary purposes.

(August 5, 2010)

# 2010年上半年我国医疗器械进出口情况

据医保商会统计，2010年上半年我国医疗器械进出口总额达100.88亿美元，同比增长27.50%，其中，出口额为65.73亿美元，同比增长26.86%；进口额为35.15亿美元，同比增长28.15%。

2010年上半年全国共有1.76万家企业经营99种（类）医疗器械，出口到215个国家和地区。在出口排名前10位的企业中，外资和合资企业就有7家。

2010年上半年，亚洲、欧洲和北美洲仍然是我国医疗器械主要出口市场，对应的出口额分别是21.64亿美元、18.38亿美元和18.78亿美元，所占比重高达89.45%。美国、日本和德国是我国医疗器械出口传统的前3大市场，2010年上半年所占比重达44.03%。

2010年上半年，我国共从93个国家和地区进口了医疗器械，欧洲是医疗器械最大进口市场，所占比重达38.59%，其中德国、瑞士、爱尔兰、法国、荷兰、英国等欧洲国家占了我国医疗器械进口十大贸易伙伴的6席。

2010年上半年，全国共有7790家企业经营医疗器械进口，进口医疗器械金额达到1亿美元的产品有9个，其中位居前三位的产品分别为:“其他医疗、外科或兽医用X射线应用设备”、“其他弥补生理缺陷残疾穿戴或植入人体的器具”、“其他医疗、外科或兽医用仪器及器具”。

（2010年8月9日）

表1.　2010年上半年中国医疗器械进出口情况
Table 1. Import and export of China's Medical Device in the first half of 2010

| | 出口情况 Export | | | 进口情况 Import | | |
|---|---|---|---|---|---|---|
| 分类 Category | 出口额（亿美元） Export Volum (Million $) | 同比增减 (%) Increase+ or Decrease- % | 所占比重 (%) Proportion % | 进口额（亿美元） Import Volume (Million $) | 同比增减 (%) Increase+ or Decrease- % | 所占比重 (%) Proportion % |
| 医疗诊断与治疗 Hospital diagnosis and treatment | 2126 | 26.76 | 32.34 | 2855 | 27.33 | 81.23 |
| 一次性耗材 Disposable consumables | 1021 | 14.84 | 15.53 | 441 | 30.45 | 12.56 |
| 口腔设备与材料 Dental equipment | 129 | 17.35 | 1.97 | 70 | 32.53 | 1.98 |
| 保健康复用品 Healthcare& Rehabilitation Products | 1191 | 27.51 | 18.12 | 53 | 56.88 | 1.5 |
| 医用辅料 Medical dressings | 2106 | 34.03 | 32.04 | 96 | 26.53 | 2.73 |
| 合计 Sum | 6573 | 26.86 | 100.00 | 3515 | 28.15 | 100.00 |

表2.　2010年上半年中国医疗器械出口十大市场
Table 2. Top 10 export destination market for China's Medical Device in the first half of 2010

| 国别地区 Country / Region | 出口额（亿美元） Export Volume (Million $) | 同比增减 (%) Increase+ or Decrease - % | 所占比重 (%) Proportion % |
|---|---|---|---|
| 美国 America | 1793 | 25.09 | 27.28 |
| 日本 Japan | 693 | 13.63 | 10.54 |
| 德国 Germany | 408 | 13.07 | 6.21 |
| 中国香港 Hong Kong China | 289 | 1.02 | 4.4 |
| 英国 Britain | 242 | 32.91 | 3.68 |
| 荷兰 Netherlands | 177 | 9.41 | 2.69 |
| 意大利 Italy | 176 | 19.48 | 2.68 |
| 韩国 Korea | 173 | 58.68 | 2.63 |
| 法国 France | 146 | 24.6 | 2.21 |
| 越南 Vietnam | 134 | 393.39 | 2.04 |
| 合计 Sum | 4231 | - | 64.36 |

表3. 2010年上半年中国医疗器械进口十大贸易伙伴
Table 3. Top 10 trade partners for China's import of Medical Device in the first half of 2010

| 国别地区 Country / Region | 出口额（亿美元） Export Volume (Million $) | 同比增减 (%) Increase+ or Decrease - % | 所占比重 (%) Proportion % |
|---|---|---|---|
| 美国 America | 10.71 | 25.06 | 30.47 |
| 德国 Germany | 6.05 | 33.49 | 17.23 |
| 日本 Japan | 5.64 | 21.77 | 16.06 |
| 瑞士 Switzerland | 1.24 | 28.96 | 3.52 |
| 韩国 Korea | 1.18 | 40.44 | 3.37 |
| 爱尔兰 Ireland | 1.00 | 51.15 | 2.85 |
| 法国 France | 0.98 | 45.65 | 2.78 |
| 荷兰 Netherlands | 0.87 | 6.56 | 2.47 |
| 英国 Britain | 0.86 | 38.76 | 2.44 |
| 墨西哥 Mexico | 0.53 | 61.79 | 1.50 |
| 合计 Sum | 29.06 | - | 82.69 |

表4. 2010年上半年中国医疗器械进口金额上亿元产品（单位：亿美元）
Table 4. Imported Medical Device with a volume exceeding $ 100 million in the first half of 2010

| 产品 Product | 进口额 Import Volume (Million $) | 同比（%） Increase+ or Decrease - % |
|---|---|---|
| 其他医疗、外壳活兽医用X射线应用设备 X-ray application equipment for other medical treatment, surgical or veterinary purposes. | 2.52 | 20.52 |
| 其他弥补胜利缺陷残疾穿戴或植入人体的器具 Miscellaneous medical equipment or apparel making up for physiological defects, or implanted instruments | 2.48 | 41.65 |
| 其他医疗、外科或兽医用仪器及器具 Apparatus and instruments for other medical treatments, surgical or veterinary purposes | 2.32 | 26.45 |
| 彩色超声波诊断仪 Chromo scope ultrasonic diagnostic equipment | 2.31 | 11.47 |
| X射线断层检查仪 X-ray tomography instruments | 2.09 | 42.04 |
| 其他针、导管、插管及类似品 Other injection needles, catheter, tubage and similar medical items | 2.07 | 25.64 |
| X光发生器等、检查用家具等9022设备 X-ray Generator, furniture for medical examination, parts for 9022 medical devices | 1.91 | 28.02 |
| 核磁共振成像装置 Nuclear Magnetic Resonance Imaging equipment | 1.63 | 45.29 |
| 实用光学射线的分光仪、分光光度计及摄谱仪 Spectrometer, spectro-photometer and spectrograph | 1.61 | 20.42 |
| 合计 Sum | 18.94 | - |

Special column 特约专栏

Provided by Johnson & Johnson Medical (China) Ltd.
强生（中国）医疗器材有限公司 供稿

# Brief introduction on FDA Discussion on the Draft 510(k) and Use of Science in Regulatory Decision Making Reports

# 美国510（K）流程再规范以及法规决策科学性讨论报告简介

In August, 2010, two preliminary reports from FDA's Center for Devices and Radiological Health (CDRH or the Center) was been releasing for public comments, recommending concrete steps they could take to advance three key objectives of a balanced public health approach: fostering medical device innovation, enhancing regulatory predictability, and improving patient safety. [Center for Devices and Radiological Health 510(k) Working Group Preliminary Report and Recommendations, and Task Force on the Utilization of Science in Regulatory Decision Making Preliminary Report and Recommendations; Availability; Request for Comments.]

Jeffery Shuren, M.D., J.D., Director of Devices and Radiological Health, highlights 10 recommendations in particular from these two documents.

**I. Fostering Medical Device Innovation**

1.Streamline the premarket pathway for lower-risk novel devices.

The process for Evaluation of Automatic Class III Designation (also known as the de novo classification process) is meant to serve as a regulatory pathway for novel devices that cannot be cleared through the 510(k) process because they lack a clear predicate, but whose risks do not warrant a premarket approval (PMA) level of review. As currently implemented, the de novo classification process tends to be associated with lengthy review timeframes and nontransparent data requirements, making it an impractical path to market for many device developers. The 510(k) Working Group recommends that CDRH make major reforms in our implementation of the de novo process, including steps to streamline the process and clarify the Center's evidentiary expectations for de novo requests.

2. Enhance science-based professional development for CDRH staff.

To accommodate the development of novel technologies, within the 510(k) context and beyond, CDRH must be able to readily tap into relevant scientific expertise in the course of our decision making. Both the 510(k) Working Group and the Task Force on the Utilization of Science in Regulatory Decision Making recommend that CDRH enhance training, professional development,

2010年8月，来自美国食品药品监督管理局（美国FDA）下属医疗器械与辐射保健中心（CDRH）的两份初步报告被发布，以便就可被用于推动公共卫生方面的三个关键目标的具体步骤和措施，向公众征求意见和建议。（这三个关键目标为促进医疗器械的创新，增强监管的可预测性和提高患者的安全）

对于这两份初步报告，CDRH主任Jeffery Shuren尤其强调了下列10项建议。

**I. 促进医疗器械的创新**

1. 简化风险较低的新医疗器械的上市前监管途径

自动归为III类医疗器械的评估程序（也被称为“重新分类程序”）是适用于一些新医疗器械的监管途径，此类新医疗器械是由于缺乏明确的参照器械而无法使用510（k）审查程序，但其风险没有达到需要进行上市前审批（PMA）的程度。目前所实施的重新分类程序的监管模式需要漫长的审查时间且数据要求不透明，使其对于许多医疗器械开发商而言并非可行的上市途径。510（k）工作组建议，CDRH应该对重新分类程序的实施方式进行重大改革，包括对流程进行简化，和澄清CDRH在重新分类申请方面需要申请者提交的证据的要求。

2.针对CDRH的职员，加强以科学为基础的专业发展

为了促进新技术的发展，在510（k）审查方面，CDRH应能够在决策过程中充分利用相关的科学专业知识。510（k）工作组和监管决策过程科学应用工作组建议，CDRH应该对CDRH职员

and knowledge-sharing among Center staff, to assure that appropriate scientific expertise and regulatory experience are brought to bear in decision making. Both groups recommend that these efforts include providing greater opportunities for staff to stay abreast of recent scientific developments and current clinical practice.

3. Establish a network of external experts to better inform the review of cutting-edge technologies.

Because it is not feasible for CDRH experts to be up-to-date on all scientific developments, particularly in newly emerging fields, it is sometimes necessary for us to supplement our in-house expertise with that of external parties. The Task Force on the Utilization of Science in Regulatory Decision Making recommends that the Center continue ongoing efforts, in keeping with the Center's FY 2010 Strategic Priorities, to develop a network of external experts using web-based social media technology. Such a network would allow Center staff to more efficiently and effectively leverage outside knowledge in order to answer important scientific questions, but would not serve in an advisory capacity.

**II Enhancing Regulatory Predictability**

4. Increase the predictability of 510(k) data needs by establishing a new "class IIb."

Within the 510(k) context, most instances where concerns have been raised by industry and Center staff generally have involved the small subset of devices for which staff requested clinical information midway through a review but where the submitter had no advance notice that such information would be needed as part of its 510(k), leading to avoidable delays. The 510(k) Working Group therefore recommends that CDRH develop guidance to define, at least as a heuristic, a subset of class II devices called "class IIb" devices, for which clinical or manufacturing information would typically be necessary to support a substantial equivalence determination. The development of a "class IIb" guidance document would help clarify, up front, what information submitters should include in their 510(k)s, so that they can plan accordingly. In so doing, it would help our review staff obtain, in a more efficient and predictable manner, the type and level of evidence they need to make reliable, well-supported decisions.

5. Create a new "Notice to Industry" tool to more rapidly communicate changes in premarket expectations.

With respect to 510(k) review and also more broadly, we as a Center may need to modify our premarket evidentiary expectations for certain types of devices over time, as science evolves and new information emerges about the risks and benefits of a given device type. Under current law, our traditional guidance development process can be cumbersome, and it has not allowed us to communicate such changes in a rapid manner. Instead, manufacturers typically learn of these changes through individual engagement with the Center, often not until after they have prepared their premarket submissions. The Task Force on the Utilization of Science in Regulatory Decision Making therefore recommends that CDRH begin to use standardized "Notice to Industry" letters to quickly communicate to an affected sector of industry when we have changed in our regulatory expectations with respect to a particular group of devices, the general nature of the change, and the rationale for the change, generally as a

加强培训、专业培养和知识共享，以确保他们能使用适当的科学专业知识和监管经验，做出正确的决定。两个工作组均建议，具体的工作应该包括给职员提供更多的机会，以了解和掌握最近的科学发展情况和当前的临床实践。

3.建立外部专家网络，以便在审查中更好地掌握和利用最先进的技术

由于CDRH的专家不可能始终了解所有最新的科学发展，特别是新兴领域的科学发展，因此在某些时候，我们有必要用外部各方的专业知识对我们的内部专业知识加以补充。监管决策过程科学应用工作组建议，CDRH应该按照CDRH2010年财政年度战略性优先事项，继续努力利用基于网络的社交通信技术开发和建立一个外部专家网络。上述网络将帮助CDRH的职员有效利用外部知识解答重要的科学问题。

**II. 增强监管的可预测性**

4. 通过建立一个新的“IIb类”医疗器械类别，增强510（k）审查数据需求的可预测性

在510（k）审查方面，其中企业界和CDRH审查人员提出疑虑的大部分案例通常均涉及一小类医疗器械。对于该类医疗器械，审查人员在审查过程中要求提供临床信息，但提交人并未在事先被告知其510（k）文件可能需要包含临床信息，因此不可避免地导致延误。510（k）工作组进一步建议，CDRH应该制定相应的指导原则，以在II类医疗器械之下建立一个“IIb类”医疗器械类别。对于“IIb类”医疗器械，临床和制造信息一般需要被提供，以支持实质等效性决定。制定“IIb类”医疗器械指导文件将帮助提交人弄清应该将哪些信息包含在其510（k）文件中，以便提交人能够相应地准备文件。同时，其还将帮助我们的审查人员以更高效和更可预测的方式获得必要的各种类别和程度的证据，做出可靠且有根据的决定。

5. 创建一种全新的“行业通告”工具，以更为快速地告知上市前审查证据预期方面的变化

在510（k）审查方面，随着时间的推移，由于科学的发展和与某个具体种类医疗器械的风险和益处有关的新信息的出现，我们（即CDRH）可能需要修改我们对于某些种类医疗器械的上市前证据的要求。依据现行法律，我们传统的指导原则制定过程可能过于繁琐，且并不允许我们及时和迅速地告知上述变化。制造商一般通过各自与CDRH的交往才得知该等变化，且经常在编制了上市前申报文件之后才获知。监管决策过程科学应用工作组因此建议，CDRH应该开始利用标准化的“行业通告”函，以便在我们改变对某一类医疗器械的监管预期时，在更为详细的指导原则被制定之前，便可快速地将上述改变的一般性质和理由告知受影响的企业。该等函件将使得制造商能够更为及时地了解我们不断变化的证据预期。

precursor to more detailed guidance. These letters would help provide greater clarity to manufacturers, in a timelier manner, about our evolving expectations.

6. Clarify the meaning of key terms in the 510(k) "substantial equivalence" review standard to improve the consistency, transparency, and timeliness of the review process.

Insufficient clarity with respect to critical terms in the statutory definition of "substantial equivalence" has, in some cases, contributed to inconsistency in CDRH's 510(k) decision making, internal and external debates, and delays in review.

As the 510(k) standard has been applied to a wider range of devices over time, including increasingly varied, complex, and potentially higher-risk technologies, the need for greater clarity has become even more pressing. The 510(k) Working Group recommends that CDRH more clearly define these terms in guidance and training for review staff and industry.

7. Establish a Center Science Council as a new governance model to assure quality and consistency in CDRH's science-based decision making.

Regulatory predictability also depends on effective and expert internal oversight. To better assure quality and consistency in CDRH's science-based decision making, both the 510(k) Working Group and the Task Force on the Utilization of Science in Regulatory Decision Making recommend that CDRH establish a Center Science Council, comprised of experienced managers and employees and under the direction of the newly created Deputy Center Director for Science position. Consistent with the President's memorandum on scientific integrity,3 this standing body would be responsible for overseeing science-based decision making across the Center, including premarket review; periodically auditing decisions and assessing program performance; and acting as a resource for staff on scientific questions, to support greater consistency in decision making and the treatment of cross-cutting issues.

**III Improving Patient Safety**

8. Require the up-front submission of more complete safety and effectiveness information to support the review of 510(k) devices.

In order to support robust and well-informed decision making within the 510(k) process, the 510(k) Working Group recommends that CDRH consider revising existing regulations to explicitly require 510(k) submitters to provide in their 510(k)s a summary of all scientific information known or that should be reasonably known to the submitter regarding the safety and/or effectiveness of the device under review. Current regulations do not expressly require submitters to provide such a summary. As a result, important relevant information may not be included in a 510(k) upon initial submission, even when that information is readily available to the submitter. Requiring this type of summary would allow review staff to more efficiently make well-supported 510(k) decisions that consider all relevant safety and effectiveness information. Including such a summary should not present a significant additional burden for submitters, many of whom typically collect this type of information in their own product development processes.

9. Create a searchable online public database to provide more detailed, up-to-date medical device information to industry, the health

6. 澄清510（k）“实质等效性”审查标准中关键术语的含义，以提高审查过程的连贯一致性、透明性和及时性

由于“实质等效性”的法定定义中，一些关键术语的含义不够明确，因此在某些情况中，造成了CDRH510（k）决策的不连贯和不一致、内部和外部争论以及审查过程的延误。随着时间的推进，510（k）标准已经被应用于大量的医疗器械，且涉及越来越多样化和复杂且存在较高风险的技术，因此对上述词语的含义进行澄清的要求已经越来约迫切。510（k）工作组建议，CDRH应该在相应的指导原则中以及在针对审查人员和整个行业的培训中，更为明确地定义此类术语。

7. 建立中心科学理事会作为一种新的监管模式，以确保CDRH以科学为基础的决策过程的质量和连贯一致性

监管的可预测性还取决于有效和专业的内部监督。为了更好地保证CDRH以科学为基础的决策过程的质量和连贯一致性，510（k）工作组和监管决策过程科学应用工作组均建议，CDRH应该建立一个中心科学理事会，且该理事会应该由经验丰富的管理人员和审查人员组成并由新设立的中心科学副主任岗位领导。遵照总统有关科学诚信的谅解备忘录，这个常设机构将负责监督CDRH内部以科学为基础的决策过程（包括上市前审查过程），定期审核决定和评估方案的实施情况，并作为可被审查人员用于解决科学问题的资源，以提高决策和处理跨部门问题方面的连贯一致性。

**III. 提高患者的安全**

8. 要求提交更为完整的安全性和有效性信息，以支持510（k）医疗器械审查

为了支持在510（k）审查过程中进行知情决策，510（k）工作组建议，CDRH应该考虑对现有的法规进行修订，以明确要求510（k）提交人在其510（k）文件中，提供相应的汇总信息. 汇总信息包含其知道或应该知道的与被审查医疗器械的安全性和/或有效性有关的所有科学信息。现行的法规未明确要求提交人提供上述汇总信息。因此，在初次提交时，重要的相关信息可能不被包含在510（k）文件中，即使提交人可获得上述信息。要求提交人提交上述汇总信息将使审查人员能够在考虑与安全性和有效性有关的所有信息的基础上，更为高效地做出有根据的510（k）审查决定。在510（k）文件中包含上述汇总信息并不会对提交人构成重大的额外负担，因为许多提交人一般均在自己的产品研发过程中收集此类信息。

9. 建立一个可检索的在线公开数据库，以便向企业界、医疗保健从业人员和患者提供更为详细的最新医疗器械信息

两个委员会均建议，CDRH应该增强我们

care community, and patients.

Both committees recommend that CDRH enhance our web-based public resources to provide industry, practitioners, and patients with ready access to meaningful, up-to-date device information that will help support informed clinical decision making and safe device use. The 510(k) Working Group recommends that CDRH make major improvements to our current online 510(k) database, so that it can serve as a searchable one-stop source for detailed information about cleared devices, including photographs and design schematics, summaries of FDA review decisions, and up-to-date device labeling. Such a database would allow prospective 510(k) submitters to more readily identify appropriate predicate devices and would provide practitioners and patients with more comprehensive and current information to support the safe use of cleared devices. Similarly, the Task Force on the Utilization of Science in Regulatory Decision Making recommends that CDRH continue to build upon our existing Transparency website to provide external parties with more information about our regulatory decisions and the science that grounds those decisions, across the total product life cycle.

10. Clarify CDRH's 510(k) rescission authority and the circumstances under which a device should not be used as a predicate.

Concerns have been raised that current FDA regulations and practice may allow for some types of predicate comparisons that are insufficient to consistently provide reasonable assurance that a device under review, subject to general and applicable special controls, is safe and effective for its intended use. The 510(k) Working Group recommends that CDRH explore the development of guidance to identify situations in which a device should not be used as a predicate, such as when the device has been removed from the market because of safety concerns. In addition, to clarify the circumstances under which CDRH would exercise our authority to rescind a 510(k) clearance to remove an unsafe device from the market and preclude its use as a predicate, the 510(k) Working Group recommends that CDRH consider issuing a rescission regulation.

The recommendations contained in these reports are preliminary. CDRH has not made any decisions on specific changes to pursue. Once their assessment of public input and other necessary reviews are completed, they will announce which improvements they intend to implement, as well as projected timelines for implementation.

基于网络的公共资源建设，以便使得企业界、从业人员和患者能够获得有意义的最新医疗器械信息，从而帮助做出知情的临床决策并确保医疗器械被安全地使用。510（k）工作组建议，CDRH应该对我们目前的在线510（k）数据库进行重大改进，以便其成为可检索的一站式数据库，可提供与通过审查的医疗器械有关的详细信息，包括照片、设计草图、美国FDA的审查决定概述以及最新的标签。上述数据库将使潜在的510（k）提交人能够更便利地找到适当的参照器械，并将为从业人员和患者提供更为全面和最新的信息，以确保通过审查的医疗器械被安全地使用。类似地，监管决策过程科学应用工作组建议，CDRH应该继续建设我们现有的网站，以便在产品的整个寿命周期内，向外部各方提供与我们的监管决定和该等决定的科学依据有关的更多信息。

10. 澄清CDRH的510（k）批文废除权限，并说明在哪些情况下医疗器械不得被用作参照器械

有些人担心，美国FDA现行的法规和实践可能会导致出现以下情况: 与某些种类的参照器械所进行的对比，并不足以连贯一致地保证被审查的医疗器械在一般性和可适用的特别控制措施下，可被安全和有效地用于其预期用途。510（k）工作组建议，CDRH应该考虑制定相应的指导原则，以说明在哪些情况下某个医疗器械不得被用作参照器械（例如当该医疗器械已经由于安全方面的担忧而从市场中被清除时）。此外，510（k）工作组建议，CDRH应该考虑发布一项批文废除法规。目的是澄清:在哪些情况下CDRH可行使废除某份510（k）批文的职权，从而将不安全的医疗器械从市场中清除，并禁止其被用作参照器械，

本报告中所包含的建议均为初步建议。CDRH并未决定进行任何具体的改变。一旦对公众意见的评估和其他必要的审查结束，CDRH将宣布其将进行哪些改进，以及各项改进行动的时间期限。

**Notes:** All Chinese information in Newsletter extracted from Newspapers and Internet. All English articles are the translations from the Chinese version.
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