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CHINA MEDICAL DEVICE NEWSLETTER

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NEWS

Hong Kong Special Administrative Region and SFDA Sign Agreement on Drug and Medical Device Administration

On May 24, the Department of Health, Hong Kong Special Administrative Region, signed an agreement with the State Food and Drug Administration in Hong Kong to further promote exchange and cooperation between the mainland and Hong Kong in drug and medical device administration.

This agreement includes strengthening exchange in administrative systems and laws and regulations on drug and medical devices, communication about product registration and safety information , GMP exchange, cooperation in personnel training and Chinese crude drug administration, and issues concerning cooperation in the supervision of clinical trials on Chinese and Western medicines.

Lin Bin'en, the Director of Health of the HKSAR Government, said that the cooperation after signing the agreement will greatly upgrade the management levels of the mainland and Hong Kong on drug and medical devices. Additionally, this agreement will expand the areas of cooperation in the safeguarding of the health of citizens in the mainland and Hong Kong. (May 31, 2010)

SFDA Convenes National Medical Device Operation and Supervision Seminar The National Medical Device Operation and Supervision Seminar was held in Beijing on May 26. Personnel responsible for medical device supervision from provinces, autonomous regions and municipalities directly under the central government discussed the problems existing in the current operation and supervision of medical devices. During the seminar, the attendees expressed their opinions and suggestions on problems demanding prompt resolution such as division of power and responsibility for operation and supervision, the issuance of business licenses for in-vitro diagnostic agents, the marking and coding of business scope, and supervision of varieties with special management demand, and also discussed Administrative Measures for Business Licenses for Medical Device Operating Enterprises (draft). This provides a reference and basis for the SFDA to formulate the laws, regulations and policies on the administration of medical device operation and improves the methods of administration of medical device operation. (May 27, 2010)

Recently-Released Notice by the SFDA on Strengthening the Administration of Medical Oxygen, to Apply Stringent Control over the Approval and Administration of Medical Molecular Sieve Oxygen-generating Equipment

With a view to further strengthening the administration of medical oxygen, the SFDA recently promulgated the Notice on Strengthening the Administration of Medical Oxygen, calling on all food and drug administrative departments to practically strengthen the administration of the use of medical molecular sieve oxygen-generating equipment. According to the SFDA arrangements, special inspections should be conducted on the molecular sieve oxygen-making equipment at the source of the oxygen for the centralized oxygen-supply system for medical institutions. For those failing to meet the standards for the devices, the user units will be immediately be asked to stop their use and handle them according to the law. This notice also asks for the maintenance of strict control over the examination and approval of medical molecular sieve oxygen-making equipment, so as to ensure the approved products meet the provisions of the laws and regulations. (April 14, 2010)

SFDA Center for Administration of Medical Device Standards Inaugurated

The inauguration of the National Institute for the Control of Pharmaceutical and Biological Products (NICPBP), bearing the brand of the SFDA Center for Administration of Medical Device Standards, was held in NICPBP on March 30, 2010.

The main functions of the new center are: to undertake routine work for drawing up medical device standards; to organize the technical committee for the standardization of related medical device specialties; to conduct the formulation and revision of medical device standards under the authorization of the SFDA; to carry out research on medical device

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standard systems and put forward suggestions on policies for medical device standards and the planning of standard programs; to deal with technical research on the denomination, classification, and coding of medical devices; to provide professional guidance on national medical device standards; and to undertake other issues assigned by the SFDA.

It was reported that, so far, China has already promulgated 180 national standards and 727 industrial standards for medical devices, and established 22 technical committees for the standardization of medical device specialties, thus providing technical support for the administration of medical devices. (March 31, 2010)

SFDA Publishes Notice on Issues Concerning Extension of 2006 Registration Certificates for Medical Devices

In order to solve the problems existing in the centralized declaration and approval for re-registration of domestic Class III and import medical devices, the SFDA issued a notice on the issues concerning the registration of domestic Class III medical devices and those from Taiwan, Hong Kong, Macao, and other Chinese regions, which were approved for registration in 2006, to the food and drug administrative bureaus of all provinces, autonomous regions, and municipalities directly under the central authority (drug administrative bureaus). The main contents include:

I. For those whose applications for re-registration were accepted before the expiration of the valid periods of the registration certificates of the medical devices but whose approval for re-registration was not completed within 90 working days, the registration certificates for medical devices promulgated by the SFDA in 2006 may continue to be used during the appropriate periods of examination and approval for the re-registration of the medical devices, but the maximum periods should not be later than December 31, 2012. The registration certificates shall not continue to be used after January 1, 2013.

II. For medical devices in the above situation, if applications for re-registration are approved after the SFDA makes its decision on approval for re-registration, applicants should use the newly-issued registration certificate for medical devices as the certificate of approval for the lawful marketing of the product; if the application for re-registration is not approved, the registration certificate for medical devices issued by the SFDA in 2006 shall not continue to be used after the expiration of the certificate.

III. For applications for re-registration accepted after the deadline of the valid period for the registration certificates of the medical devices, the registration certificate for medical devices issued by the SFDA in 2006 shall not continue to be used after the expiration of the certificate.

(April 12, 2010)

国家食品药品监督管理局发布关于2006年医疗器械注册证书延期事宜的通知

为解决目前境内第三类和境外医疗器械集中申报重新注册审批中的问题，国家食品药品监督管理局日前向各省、自治区、直辖市食品药品监督管理局（药品监督管理局）就2006年已获准注册的境内第三类医疗器械以及台湾、香港、澳门地区和境外医疗器械注册有关事宜下发了通知，内容如下：

一、凡在医疗器械注册证书有效期截止日前已受理重新注册申请、未在90个工作日内完成重新注册审批的，国家局2006年颁发的医疗器械注册证书在相应医疗器械重新注册审批期间可以继续使用，但最长不超过2012年12月31日，2013年1月1日后其注册证书不得继续使用。

二、对于上述情形的医疗器械，国家局做出重新注册审批决定后，获准重新注册的，应当凭新核发的医疗器械注册证书作为产品合法上市的批准证明文件；未获准重新注册的，国家局2006年颁发的医疗器械注册证书有效期届满后不得继续使用。

三、对于在医疗器械注册证书有效期截止日之后受理重新注册申请的，国家局2006年颁发的医疗器械注册证书有效期届满后不得继续使用。 (2010-04-12)

SFDA Release Clarifying the Administrative Classification of Bone Cement Thimble Assemblies and Vertebral Body Expansion (Shaping) Devices

For the purpose of further strengthening the administration of bone cement thimble assemblies and vertebral body expansion (shaping) devices and guaranteeing the safety and efficiency of related products, the SFDA released a notice on April 6, making clear the classification of the administration of bone body thimble assemblies and vertebral body expansion (shaping) devices.

I. Bone cement guns, also known as bone cement injectors, bone cement fillers, bone cement mixers, etc., including disposable and reusable products, and the orthopedic apparatus used for blending bone cement and injecting (feeding) bone cement into marrow cavities shall be administrated as Class II medical devices.

II. Percutaneous puncture devices used for percutaneous puncture and preliminary establishment of operating channels for entering vertebral bodies shall be administrated as Class II medical devices.

III. Devices for establishing work passages into vertebral bodies used for vertebral body figuration and resetting systems, including guide wire positioning, expansion bushing, high-precision drilling, work columns, etc., mainly playing the role of injecting bone cement and establishing work passages for accessing vertebral bodies, shall be administrated as Class II medical devices.

IV. Bone expanders, which are expandable devices in tubular conductive structures for sacculus expanding, or in mechanical expansion mode, or in metallic mesh bags and other expansion structures used for intra-vertebral expansion for compression fractures, resetting into hollow work passages fed with fillers, and restoring vertebral height, shall be administrated as Class III medical devices.

From the date of promulgation of the notice, the provisions on the classification of above similar products in the published classification and definition documents shall be abolished. For the products approved for registration, if inconsistent with the above administration classification, applications for change and re-registration shall be submitted according to the provisions in Article 35 of the Management Measures for Registration of Medical Devices. (April 14, 2010)

国家食品药品监督管理局发布明确骨水泥套管组件和椎体扩张（成形）器械管理类别的通知

为进一步加强对骨水泥套管组件和椎体扩张（成形）器械的监管，保障相关产品的安全和有效，国家食品药品监督管理局4月6日发出通知，对骨水泥套管组件和椎体扩张（成形）器械的管理分别进行了类别明确。

一、骨水泥枪，或称骨水泥注入器、骨水泥填充器、骨水泥搅拌器等，包括一次性和可重复使用产品，用于混匀骨水泥，并将骨水泥注入（输送到）骨髓腔的骨科工具。按照二类医疗器械管理。

二、经皮穿刺器械，用于经皮穿刺，初步建立进入椎体的工作通道。按照二类医疗器械管理。

三、建立进入椎体的工作通道器械，用于椎体成形复位系统，包括有引导丝定位、扩张套管、高精度钻、工作套管等，主要起到为注入骨水泥而建立进入椎体的工作通道的作用。按照二类医疗器械管理。

四、骨扩张器，为一可膨胀装置，可以是扩张球囊导管结构，或机械扩张方式，或金属网状袋等其他扩张膨胀结构，用于压缩性骨折等的椎体内膨胀，复位形成一个中空的、可供充填物填充的一个工作通道，回复椎体高度。按照三类医疗器械管理。

自通知发布之日起，已发布的分类界定文件中上述同类产品的分类规定予以废止。已经批准注册的产品，与上述管理类别不一致的，按照《医疗器械注册管理办法》第三十五条的规定申请变更重新注册。

(2010-04-14)

State Administration of Traditional Chinese Medicine Release: Suggestions on Promoting the Development of Traditional Chinese Medicine Diagnosis and Treatment Equipment

On May 6, the State Administration of Traditional Chinese Medicine (SATCM) published Suggestions on Promoting the Development of Traditional Chinese Medicine Diagnosis and Treatment Equipment, encouraging the participation of Traditional Chinese Medicine institutions, enterprises, research institutes, universities and colleges, etc., intensifying efforts on research and development in key fields such as integrated equipment and diagnosis equipment, changing the situation in which current Traditional Chinese Medicine diagnosis and treatment equipment is simple and homogenous, and enabling Traditional Chinese Medicine diagnosis and treatment equipment to play a more important role in making use of the advantages of Traditional Chinese Medicine, enriching the clinical diagnosis and treatment methods of Traditional Chinese Medicine, and improving the curative effect of Traditional Chinese Medicine.

Traditional Chinese Medicine diagnosis and treatment equipment refers to the instruments, equipment, apparatuses, materials, and other appliances (including the necessary software) applied in diagnosis and treatment activities under the guidance of the theories of Traditional Chinese Medicine. The SATCM calls for the building up, through years of effort, of a group of development platforms for Traditional Chinese Medicine diagnosis and treatment equipment, forming a group of production bases and leading enterprises of Traditional Chinese Medicine diagnosis and treatment equipment, and promoting a group of Traditional Chinese Medicine diagnosis and

国家中医药管理局发布《关于促进中医诊疗设备发展的意见》

5月6日，国家中医药管理局发布了《关于促进中医诊疗设备发展的意见》，鼓励中医医疗机构、企业、科研院所、大专院校等多方面参与，加大对集成设备、诊断设备等重点领域的研发，改变目前中医诊疗设备类型单一、同类化严重的现象，使中医诊疗设备在保持发挥中医药特色优势、丰富中医临床诊疗手段、提高中医临床疗效方面发挥更大作用。

中医诊疗设备是指在诊疗活动中，在中医理论指导下应用的仪器、设备、器具、材

treatment equipment.

The SATCM emphasizes that the manufacturing enterprises of Traditional Chinese Medicine diagnosis and treatment equipment should strictly standardize the production processes of medical devices and ensure the quality of marketed products according to the related laws and regulations on GMP for medical devices formulated by the SFDA. The administration shall assist related departments in formulating the standards for Traditional Chinese Medicine diagnosis and treatment equipment and the guidelines on product registration and technical inspection, including the service items of Traditional Chinese Medicine diagnosis and treatment equipment meeting conditions within the range of medical insurance, and shaping a policy environment favorable to the development of Traditional Chinese Medicine diagnosis and treatment equipment.

(May 7, 2010)

料及其他物品（包括所需软件）。国家中医药管理局提出，要通过几年的努力，建立一批中医诊疗设备的开发平台，形成一批中医诊疗设备的生产基地和龙头企业，推广一批中医诊疗设备。

国家中医药管理局强调，中医诊疗设备生产企业应严格按照国家食品药品监管局制定的医疗器械质量体系管理相关法规，严格规范医疗器械生产过程，确保上市产品的质量。国家中医药管理局将协助有关部门开展对中医诊疗设备的标准和产品注册技术审查指导原则的制定工作，将符合条件的中医诊疗设备服务项目纳入医保范围，营造有利于中医诊疗设备发展的政策环境。（2010-05-07）

Industrial Standards for Four Biochips Take Effect from June 2011

SFDA issued on Dec 30,2009,a notification of implementing the 80 industrial standards including the Medical Endoscope Rigid Endoscope, Part IV: Basic Requirements, These industrial standards will be implemented since June 1,2011. including a microarray chip used for IVD purposes, an aldehyde substrate used for biochips, a DNA microarray chip used for IVD purposes, and a laser confocal scanner. These standards are expected to be put into practice from June 1, 2011

As a new, multi-disciplinary high technology, biochip technology has been extensively applied in a wide variety of fields such as the life sciences, medical and clinical care, epidemic prevention, drug screening, and food safety. Today, China has achieved a leapfrog development in the research and development, production and application of biochip technology, and has achieved a considerable industrialized scale. It is especially important therefore to formulate the industrial standards which can guarantee the ordered development of standardized management of the biochip industry.

China's biochip research and development has had a history of ten years. So far, the biochip research and development and industrialization base, integrating technical innovation, achievement conversion, comprehensive service and training of talent into a whole, and at an advanced international level, has taken shape on the whole. Capital Biochips, with the largest industrialized scale, has established a systematic biochip technical service platform of "quaternity" (genes, proteins, cells, and organisms), developed nearly 60 products in four series (disease diagnosis biochips, supporting apparatus and equipment, reagents and consumables, and software and data) with international competitiveness and independent intellectual property rights; among which, many biochip products appeared internationally and are exported to more than 20 countries and regions.

(May 5, 2010)

4项生物芯片行业标准2011年6月起施行

国家食品药品监督管理局2009年12月30日发布了关于实施YY 0068.4-2009《医用内窥镜硬性内窥镜 第4部分：基本要求》等80项医疗器械行业标准的公告，该80项行业标准将于2011年6月1日起施行。其中包括"体外诊断用蛋白质微阵列芯片"等4项生物芯片行业标准，其标准编号、名称分别为：YY/T 1151-2009《体外诊断用蛋白质微阵列芯片》、YY/T 1152-2009《生物芯片用醛基基片》、YY/T 1153-2009《体外诊断用DNA微阵列芯片》、YY/T 1154-2009《激光共聚焦扫描仪》。

生物芯片技术作为一项多学科交叉的高新技术，已广泛应用于生命科学、医学和临床医疗、卫生防疫、药物筛选、食品安全等多个领域。目前，我国生物芯片技术在研究开发和生产应用方面已经实现了跨越式发展，并具备了一定的产业化规模，制定行业标准就显得尤为重要，可以使生物芯片产业规范化管理得到有序发展。

我国生物芯片研发现已经历10个年头的发展，基本建成了集技术创新、成果转化、综合服务、人才培养于一体，具有国际先进水平的生物芯片研究、开发和产业化基地。作为产业化规模最大的博奥生物现已建立起了包括基因、蛋白质、细胞和组织"四位一体"的系统化生物芯片技术服务平台，研制开发出了具有自主知识产权的疾病诊断生物芯片、配套仪器设备、试剂耗材、软件数据库等4个系列近60项具有较强国际竞争力的产品，其中多种芯片产品属国际首创，并出口20多个国家和地区。（2010-05-05）

955 NICPBP Medical Device Items Accredited by SFDA

The SFDA recently accredited 260 passive medical devices, 106 active medical devices, and 589 in vitro diagnostic reagent products of the National Institute for the Control of Pharmaceutical and Biological Products (NICPBP) with a valid term of five years. This is another big leap of the NICPBP after the accreditation of medical device inspection by the SFDA in 2004. In particular, a new breakthrough has been made in passive medical device inspection. This institute now has the capability of testing general electrical safety; clinical trialing equipment; infrared, microwave, medium and low-frequency physical therapies; high-frequency surgery; lasers; ophthalmological optics; and physiological electronic medical devices. (May 27, 2010)

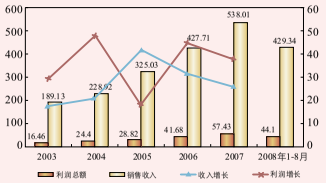
Medical System Reform Drives RMB 16B Medical Device Investment

The new medical and health system reform scheme was announced on April 6, 2009. According to this scheme, China will invest RMB 850 billion to promote medical and health system reform during 2009~2011. This big cake of new medical and health system reform has triggered competition between domestic and international medical device and medical software manufacturers.

Medical Industry Welcomes Development Opportunity

The medical device industrial market in China has developed rapidly in recent years. During 2003~2007, the annual growth rate of industrial sales revenues reached 27.08% and the annual growth rate of profit went up to 33.73%. In 2007, China had in total 298 private medical device enterprises, 240 foreign and Hong Kong, Macao and Taiwan invested enterprises, only 36 state-owned enterprises and 25 collective enterprises.

Industrial Income and Profits of China Medical Device Industry (Unit: RMB 100 million, %)



Source: State Statistics Bureau

The promulgation of the new medical and health system reform scheme will once again hasten the expansion of the medical market. The new medical and health system reform scheme was announced on April 6, 2009. It was made clear that China will invest RMB 850 billion to promote medical and health system reform during 2009~2011. In the next three years, the central government will support the construction of approximately 2000 county-level hospitals as a priority, accomplish the construction of 29,000 township health centers, and support the reconstruction or expansion of 5,000 central

中国药品生物制品检定所955个医疗器械项目获国家食品药品监督管理局检测资格认可

近日，国家食品药品监督管理局认可了中国药品生物制品检定所（简称：中检所）260个无源医疗器械、106个有源医疗器械、589个体外诊断试剂产品和项目检测资格,有效期5年。这是继2004年获国家食品药品监督管理局医疗器械检测资格认可，中检所在医疗器械检测领域的又一次飞跃，特别是有源医疗器械检测领域实现了新的突破，具备了通用电气安全、临床检验设备、红外、微波、中低频理疗、高频手术、激光、眼科光学、电生理等有源医疗器械的检测能力。（2010-05-27）

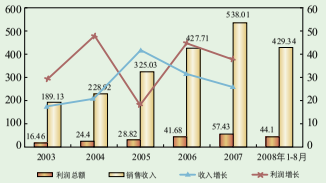
医改将带动160亿医疗器械投入

2009年4月6日，新医改方案正式对外公布，根据该方案，2009年至2011年，中国将斥资人民币8500亿元推动医疗体系改革。"新医改"大蛋糕引发中外医疗器械和医疗软件厂商摩拳擦掌。

医疗行业迎来发展机遇

近年来中国医疗器械行业市场快速发展，2003—2007年间，行业销售收入年平均增速为27.08%，利润年平均增速为33.73%。2007年，中国共有298家私营医疗器械企业、240家外商及港澳台投资企业，国有企业仅36家、集体企业25家。

中国医疗器械行业工业收入与利润（单位：亿元，%）



来源：国家统计局

新医改方案的出台，将再次催生医疗市场的扩容。2009年4月6日，新医改方案正式公布，明确2009—2011年，国家将出资人民币8500亿元推动医疗体系改革。未来三年内，中央将重点支持2000所左右县级医院建设，2009年将完成2.9万所乡镇卫生院建设，支持改扩建5000所中心乡镇卫生院。虽然8500亿元的具

township hospitals. Although it remains unclear how the RMB 850 billion will be distributed, it is generally believed among insiders that the medical device and medical software industry will benefit from the new medical system reform. According to an IDC estimate, investment in medical IT hardware and software and the service market in China will reach more than RMB 12 billion by 2010. Experts estimate that investment in medical devices driven by the new medical system reform will reach RMB 16 billion and investment in medical informatization will be at least RMB 10 billion.

The huge potential of the medical market in China will attract more and more manufacturers to participate in the competition. The domestic and foreign manufacturers among them will be in a difficult position. The ratio of the output values between the medical device industries and the pharmaceutical industries in the developed countries is 1:1.9 while in China it is only 1:5. In line with the continuous development of the national economy, medical institutions will discard old and inferior medical devices. According to statistics, among the grass-roots medical institutions accounting for more than 80% of the medical institutions in China, approximately 15% of equipment was made around the 1970s and 60% was made before the mid 1980s. The development potential of the Chinese medical market will attract more and more manufacturers to join the competition in this field.

In the rural medical device market, after-sales service may be the key to success. Unlike county-level hospitals, township hospitals are short of equipment and talents. Good after-sales service is therefore very important. At present, damage and waste resulting from shortage of supporting services has appeared. Good after-sales service should include personnel training, equipment repair, supply of fitting, etc. In the future, governments at all levels should take after-sales service of equipment as an important reference index. Enterprises should penetrate deeply into the end users and establish after-sales service points in the regions, with concentration on their business, to demonstrate their advantages.

In the future medical informatization market, the integration of the industrial chain and the medical IT resources will become a development trend. Competition pressure will urge the integration of medical industrial informatized products and service providers. As the technology continuously develops and becomes mature, sharing complementary advantages and application integration among manufacturers will become the key point of competition in the future. The construction of medical informatization in China will push ahead the trans-industrial integration of medical IT resources as well.

Foreign-funded Medical Device Enterprises Focus on Academia and Research and Development

According to the statistics of the China Chamber of Commerce for the import and export of Medicines and Health Products, the gross exports of more than 4000 foreign-invested enterprises has dominated “half of the country” of China’s medical device exports. China has become an important production base for foreign-invested enterprises. Along with the announcement of the new medical system reform scheme, foreign-funded enterprises have gradually placed research and development at the top of their expansion strategies. The year 2009 was the last year in which foreign-invested enterprises constructed bases in China on a large scale. In 2010, on the other hand, investment by foreign-funded enterprises in academic institutions and research and development will exceed their investment in production.

From Production Bases to Academic Centers

Before 2010, nearly all the foreign-funded enterprises expanded their production bases in China. Take Siemens as an example; its Shanghai International Medical Park has developed into the largest medical equipment base in China. At the end of last year, Phillips also began construction of a production base in Suzhou.

Beginning in 2010, foreign-funded enterprises have not been spending their money on the construction of production bases. The expansion and construction of academic centers have become the focus of leading foreign-invested medical device enterprises.

Johnson & Johnson (China) Medical Device Co., Ltd. is taking academic cooperation and training as its focus for development in 2010. Its CEO Mr. Xie Wenjian said, “When medical system reform in China takes improvement of the level of the basic medical facilities as the important direction for reform, actively and effectively supporting improvement of the skills of physicians is an important way to achieve this goal. The construction of the Shanghai Academic Center symbolizes that we are moving closer to our goal.”

According to information from an insider in Johnson & Johnson, the capacity of the expanded Shanghai Academic Center will be increased by nearly 100% and its area will be increased by 30%. As an important component of the localization strategy of Johnson Medical China, the Shanghai Academic Center will carry out academic activities aimed at the present situation and trends in the medical and health sector in China.

Directed at the Grassroots Market

As for the march into the grassroots medical market in China, it will be very difficult for existing high-value products from foreign-invested enterprises to find opportunities. In order to tackle the grassroots market, foreign-funded enterprises have begun to develop pertinent, grassroots-oriented medical equipment and informatization solutions.

General Situation of the Medical Device Export Market in China as of January 2010

As of January 2010, China has exported medical devices to 186 countries and regions, with the exports amounting to US$ 1.0199751 billion. There were 19 countries and regions to which more than US $10 million was exported, including mainly the USA, Japan, Germany, Hong Kong, Britain, the Netherlands, Australia, South Korea, Italy, and Spain. The top ten export countries and regions accounted for 66% of the exports.

Top Ten Export Countries and Regions for Chinese Medical Devices as of January 2010

Rank	Country	Export Amount (US$ 10,000)	Export Amount on Year-on-year Basis (%)	Proportion of Export Amount (%)
-	World	101997.51	10.75	100
1	USA	27088.54	6.91	26.56
2	Japan	13214.39	23.16	12.96
3	Germany	7031.29	3.65	6.89
4	Britain	3732.04	15.45	3.66
5	Hong Kong	3703.2	-18.29	3.63
6	Netherlands	3281.53	5.12	3.22
7	Italy	2833.96	25.83	2.78
8	France	2393.48	-0.38	2.35
9	South Korea	2113.85	5.56	2.07
10	Spain	1918.07	21.31	1.88

外资医械企业聚焦学术研发

据中国医药保健品进出口商会统计，现有4000多家外商投资企业的出口总额已连续多年占据我国医疗器械出口的“半壁江山”。中国成为外资企业重要的生产基地。随着新医改方案的出台，外资企业已经逐渐把研发放在公司拓展战略的首位，2009年是外企在华大规模建设基地的最后一年，而在2010年，外资企业在学术和研发上的投入将超过在生产上的投入。

从生产基地到学术中心

2010年以前，几乎所有外企都在扩建其在中国的生产基地。以西门子为例，其上海国际医学园区如今已发展成为中国最大的医疗设备基地。去年底，飞利浦也开始了其在苏州生产基地的建设。

而从2010年开始，外企已经不再把资金花在生产基地建设上，学术中心的扩建和新设学术中心则成为主要外资医械企业的工作重点。

强生（中国）医疗器材有限公司把学术合作和培训当做2010年公司发展的重点。其总裁谢文坚先生表示：“当中国医疗体制改革把提高基础医疗设施水平当作重大改革方向的时候，积极、有效配合提高医师技能是实现这一目标的重要途径。上海学术中心的扩建落成，标志着我们距离实现这一目标更进了一步。”

据强生方面人士介绍，扩建后的上海学术中心容量将增加近100%，面积增加逾30%。作为强生医疗中国本地化战略的重要组成部分，上海学术中心将针对中国医疗卫生现状及趋势开展学术活动。

直指基层市场

如果进军中国基层医疗市场，外资企业现有的高价产品很难有机会。为了开拓基层市场，外资企业纷纷开始有针对性地研发面向基层的医疗设备和信息化解决方案。

2010年1月，我国医疗器械出口市场概况

2010年1月，我国向186个国家和地区出口医疗器械，出口额为101997.51万美元，出口额达1000万美元以上的国家和地区为19个，主要包括美国、日本、德国、中国香港、英国、法国、荷兰、澳大利亚、韩国、意大利和西班牙等。出口额排名前十的国家和地区占出口比重66%。

2010年1月，我国医疗器械出口额前十位国家和地区情况

排名	国别	出口额（万美元）	出口金额同比(%)	出口金额占比(%)
-	全球	101997.51	10.75	100
1	美国	27088.54	6.91	26.56
2	日本	13214.39	23.16	12.96
3	德国	7031.29	3.65	6.89
4	英国	3732.04	15.45	3.66
5	香港	3703.2	-18.29	3.63
6	荷兰	3281.53	5.12	3.22
7	意大利	2833.96	25.83	2.78
8	法国	2393.48	-0.38	2.35
9	韩国	2113.85	5.56	2.07
10	西班牙	1918.07	21.31	1.88

General Situation of the American Medical Device Administration (I)

Beginning in 1938, the United States incorporated medical devices into the range administrated by the FDA. The Radiation Control for Health and Safety Act was promulgated in 1968. Strictly speaking, systematic management of medical devices dates from the publication of The Medical Device Amendment of 1976. The administrative body is the CDRH (The Center for Devices and Radiological Health) of the FDA. Due to its long history of management and operation and its perfect management system, it has achieved a certain level of authority internationally.

According to the related laws and regulations on medical device administration, the medical device products within the range of the statutory concept should obtain FDA accreditation or approval before being sold on the American market; at the same time, the US customs are liable for inspection of the medical device commodities accessing the American market, such as the FDA approval document (Tariff Act, part 141). Since there is no mark of recognition or approval for market access, the medical device products produced by American domestic enterprises cannot be supervised in a timely manner. The medical device products manufactured in the US are not restricted by FDA authorization or approval, nor are they restricted by inspections by the US customs. Therefore, it is unnecessary for medical device products imported from the US to be approved by the FDA.

The FDA emphasizes application quality in terms of usage management. For example, for medical devices qualified for marketing, accidents can occur in use, causing harm to patients and users. The FDA implements a system which charges medical devices in the case of adverse events which investigates, analyzes, and assesses adverse events and instructs manufacturing enterprises to improve or stop production, marketing and use; if necessary, recalls of the marketed products; the declaration of adverse events at regular intervals, and publishing of the results of reassessment.

There are many standards for the safety and quality of medical devices in the US. Most of them are formulated by non-official bodies. The representative AAMI (Association for the Advancement of Medical Instrumentation) standard calls for the establishment of a quality management system for medical equipment and defines the requirements for goals and specifications. It mainly applies guidance from ISO13489 and ISO13488. The contents include various standards ranging from production to use, in which medical equipment management and the electric safety index are adopted by the medical engineering departments of hospitals.

Apart from applying the above policies to safeguarding research and development, production, and circulation of medical equipment, the American government has also stipulated that all hospitals should establish hospital qualification and certification joint committees and clinical engineering departments. The hospital qualification and certification joint committee is responsible for the safety of medical equipment and its examination and approval, and implementation and supervision of an effective plan for the whole hospital. The specific work on the quality of medical devices is to be managed and executed by the clinical engineering technical departments.

Generally, American medical device management and supervision institutions include the Department of Commerce, the FDA, and HIMA. They co-operate with each other within their respective functional areas; however, according to the Federal Food, Drug and Cosmetic Act (FFDCA) of 1938, the FDA is the leading institution for medical device administration.

美国医疗器械管理概况（一）

美国于1938年开始，将医疗器械纳入FDA管理范围，1968年发布《旨在保健和安全的辐射性控制性》（Radiotion Control for Health and Safety Act）。严格地说，对医疗器械的系统管理，应从1976年发布《医疗器械修正案》（The Medical Device Amendments of 1976，MDA）算起。管理机构是FDA的CDRH。由于其管理运行历史较长，管理体系又比较健全，在国际上有一定权威性。

按相关管理法规，法定概念范围内的医疗器械产品，在美国市场销售时都应获得FDA认可或批准；同时，美国海关有责任对进入美国市场的医疗器械商品进行检查，如有无FDA认可的文件等（tariff act，part 141）。由于无认可或批准进入市场的标志，美国境内企业生产的医疗器械产品并不能及时接受监督，美国出品的医疗器械产品既不受FDA认可或批准的制约，也不受美国海关的检查制约，因此，从美国进口的医疗器械产品未必已通过FDA的认可。

FDA对于使用管理则强调应用质量的反映。如合格上市的医疗器械，在使用中出现对患者和使用人员造成伤害的事故，美国FDA实施医疗器械不良事件控告制度。对不良事件进行调查、分析、评价，责令生产企业改进或停止生产、销售、使用，必要时召回已上市产品，并不定期地通报不良事件情况，公布再评价结果。

美国对医疗器械的安全与质量的标准很多，大多由非官方机构制定。比较有代表性的美国医疗仪器发展协会（AAMI）标准，要求建立医疗设备质量管理体系，规定目标规范要求。其主要应用ISO13489和ISO13488指南，内容包括从生产到使用的各种标准，其中医疗设备管理与电气安全指标为医院医学工程部门采用。

美国政府除采用上述政策把好医疗设备的研制、生产和流通关以外，还规定各医院都要成立医院资格鉴定联合委员会和临床工程部。医院资格鉴定联合委员会负责全院医疗设备的安全性和有效性计划的审定、实行和监督工作；医疗设备质量保证的具体工作，应由临床工程技术部门负责管理和实施。

总的来说，美国医疗器械管理和监督的机构包括商务部(DC)、FDA以及医疗卫生工业制造商协会(HIMA)，它们在各自的职能范围内相互合作。但是根据1938年的《联邦食品、药品和化妆品法》，医疗器械监管的主要机构是FDA。

A New Hot Spot on the International Medical Device Market: New Medical Textile Raw Materials

As materials science and technology makes constant progress, new compound textile raw materials suitable for special medical purposes have been successively developed. The new medical textiles made from these raw materials are changing the clinical treatment mode. The new products will therefore become a new hot spot on the international medical device market. Representative new medical textile materials are exemplified below:

Multi-purpose Polyester-Wire Hollow Tubes

An American company has successfully developed a new material - a kind of intertwined hollow tubular material, woven from high-strength polyester (a common chemical fiber material), rayon, and wire. It has very extensive applications in clinical treatment, such the recovery of ruptured vessels, replacing impaired mitral valves in hearts, as "prosthetic" implantation materials, etc.

A New High-strength Chemical Fiber Material as an Alternative to Metal Materials

This product is a new compound chemical fiber raw material product made from two chemical fiber materials (aryl polyether ketone and high-strength polythene). This kind of high-strength chemical fiber compound material can not only be used for processing medical textile materials requiring a certain strength and elasticity, such as artificial blood vessels, but also used for replacing implantation prosthetic devices made from metal materials, including stainless steel, titanium, platinum, and alloys of nitinol.

New Medical Textile Raw Materials Absorbable by Humans

The new raw materials PLA (polylactic acid) and PEG (polyethylene glycol), used to produce medical textile and other implantable medical device products, have been approved for use. We've learned that the two kinds of new materials can be used to produce new cellular or compact implantation materials which have multiple new applications in clinical treatment.

国际医械市场新热点 新型医用纺织物原料

随着材料科学技术日新月异地进步，适合特殊医疗用途的新型复合纺织品原料陆续被开发出来。用这些原料制成的新型医用纺织物，正改变着现有临床治疗模式。因此，这些新产品将成为国际医疗器械市场的新热点产品。有代表性的新型医用纺织品新型材料列举如下：

多用途聚酯—金属丝空心管状物

美国一公司新近研制成一种利用高强度聚酯（常用化纤材料）人造丝与金属丝编织成麻花状的空心管状织物新材料。它在临床医疗中有非常广泛的用途，如：用于血管破裂的修复或代替受损的心脏二尖瓣作为"假体"植入材料等等。

可替代金属材料的高强度化纤新材料

该产品系用芳基聚醚酮与高强度聚乙烯两种化纤材料加工而成的新型复合化纤原料产品。这种高强度化纤复合材料既可用于加工人造血管等需要有一定强度和弹性的医用纺织品材料，也可代替不锈钢、钛、铂和镍钛诺合金等金属材料制成的植入式假体器械产品。

可被人体吸收的新型医用织物原料

可用于生产医用织物等植入器械产品新原料为聚乳酸（PLA）和聚乙二醇（PEG）已被批准使用。据介绍，利用这两种新材料可制作出多孔状或紧密型的新型植入式材料，在临床医疗中具有多种新用途。

Notice of Meeting

Notice of the 2010 Medical Device Administration International Forum

In order to strengthen communication on domestic and international medical device laws and regulations, publicize China's laws and regulations and policies on medical device administration, and act in concert with the promulgation of such rules and regulations as the new 2010 Regulations on Administration of Medical Devices and the supporting Management Measures for Registration of Medical devices, the China Centre for Pharmaceutical International Exchange (CCPIE) will convene the Medical Device Administration International Forum in Beijing on September 7-10, 2010. This forum will provide an effective means for Chinese medical device administrative departments to disseminate and implement the laws and regulations in China on medical devices, enable relevant foreign departments and enterprises to obtain a general picture of China's laws and regulations, help relevant domestic units recognize the trends in international medical device administration, trace the development of new and high technology medical devices and appropriate technical inspection methods and means, and learn and draw support from the foreign laws

会议通知

2010医疗器械监督管理国际论坛参会通知

为加强国内与国际医疗器械法规间的交流，宣传中国医疗器械监管法规政策，同时配合2010年新的"医疗器械监督管理条例"及其与之配套的新的"医疗器械注册管理办法"等部门规章的颁布实施，中国医药国际交流中心将于2010年9月7—10日在北京召开医疗器械监督管理国际论坛。此论坛将为中国医疗器械监督管理部门宣贯中国医疗器械法规提供有效途径，让国外相关部门及企业更快更全面地了解我国法规，让国内有关单位了解国际医疗器械监管动态，跟踪医疗器械高新技术的发展及其相应的技术审查方法和手段，学习并借鉴国外医疗器械监管法规和先进经验。论坛拟邀请相关国家政府机

and regulations and advanced experience in medical device administration. Relevant persons from government bodies, medical device evaluation institutions, testing institutions, scientific research units, etc. will be invited to attend and deliver speeches.

For more details, please visit: http://www.ccpie.org

Notice on the Launch of the Second Seminar on Risk Management of Medical Devices in China

To communicate and discuss the application of risk management in the administration and use of medical devices after marketing and the achievements made and to promote the safe and rational use of medical devices, the SFDA Center for Drug Evaluation and the SFDA Training Center plan to launch the second seminar on the risk management of medical devices in China, in Beijing on September 27-28, 2010. The theme of this meeting will be to explore adverse event monitoring and the risk management of high-risk medical devices. For the time and place of the meeting, please see the notice to be published later in July.

Web link: http://www.cdr.gov.cn.

构人员以及医疗器械审评机构、检测机构、科研单位等有关人员出席并作演讲。详情请见：http://www.ccpie.org

关于举办第二届中国医疗器械风险管理研讨会的通知

为交流探讨风险管理在医疗器械上市后监管和使用中的应用模式和取得的成果，促进医疗器械安全合理使用，国家食品药品监督管理局药品评价中心和国家食品药品监督管理局培训中心拟于2010年9月27—28日在北京举办第二届中国医疗器械风险管理研讨会。会议主题为高风险医疗器械不良事件监测与风险管理模式探讨，会议时间和地点请见7月下旬通知。网站链接：http://www.cdr.gov.cn

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

Clinical evaluation overview on EU and US clinical regulation

欧美医疗器械临床评价及临床试验的相关规定概况

If a device need clinical evidence to evaluate the un-determined risk during risk management, what can be provided as these evidences?

According to the GHTF SG5/N2R8:2007: clinical evaluation, below forms of evidence shall be crucial to support the risk analyses. We shall clearly bear in mind the key definitions and its relationships:

Clinical Data (not necessarily from investigation): Safety and/or performance information that are generated from the **clinical use** of a medical device.

Clinical Evaluation (processed clinical data): The assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer.

Clinical Evidence = Clinical Data + Clinical Evaluation

Clinical Investigation: Any **systematic** investigation or study in or on one or more human subjects, undertaken to assess the safety and/or performance of a medical device. However as the clinical data used as the clinical evidence doesn't necessarily come from clinical investigation, while other sources are available from literature searching and clinical experience and those data are sufficient to prove the performance and safety, clinical investigation may not be needed. As stated in the GHTF document: "Clinical investigations are necessary to **provide the data not available through other sources** (such as literature or preclinical testing) required to demonstrate compliance with the relevant Essential Principles (including safety, clinical performance and acceptability of risk/benefit ratio associated with its use). When a clinical investigation is conducted, the data obtained is used in the clinical evaluation process and is part of the clinical evidence for the device"

如果某种医疗器械需用临床证据来对其在风险管理过程中的未确定风险进行评估，那么哪些资料可以作为临床证据来提供呢？

根据《GHTF SG5/N2R8:2007:临床评估》的规定，以下形式的临床证据对支持风险分析至关重要。这些形式的临床证据及其定义对了解如何进行安全性评价有重要的意义。

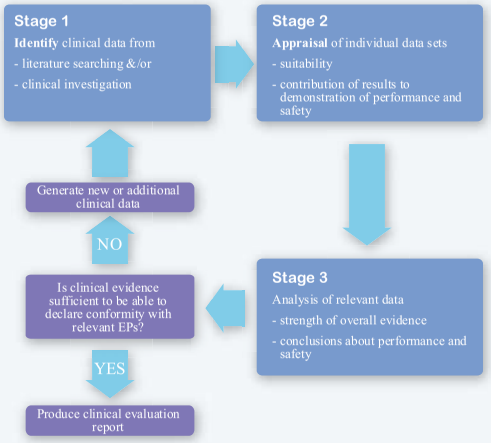
临床数据（不一定来自临床试验）：通过在临床上使用该医疗器械而获得的安全性和/或有效性的数据。

临床评估（经过处理的临床数据）：当器械按生产商的规定使用时，通过对医疗器械临床数据进行的评估与分析，来确认其临床安全性和有效性。

临床证据=临床数据+临床评估

临床试验：临床试验是指对一个或多个人体实验对象进行的旨在评估医疗器械安全性及/或有效性的系统性试验或研究。但是，作为临床证据的临床数据不一定必须来自临床试验。如果通过文献检索、临床经验等其它途径获得的数据足以证明其有效性和安全性，则可能无需临床试验。正如《GHTF SG5/N2R8:2007:临床评估》所述："**只有在通过其他途径**（如文献或临床前试验）**无法获得足够数据**来证明其符合安全性及有效性原则（包括与其使用相关的安全性、临床效果以及风险/收益比的可接受程度）的情况下，才有必要进行临床试验。在开展临床试验时，所获数据用于临床评估并构成器械临床证据的一部分。

那么临床评估的重要性何在？临床评估可以用来验证医疗器械在正常使用条件下是否能达到其预期效果；以及与预期收益相比，其已知的、可预见风险和不良反应是否已削减到最小程度，并处在可接受的风险范围内；对器械有效性和安全性，即产品标签和使用说明上所标称的内容是否都获得了适当证据的支持。关于临床数据搜集的主要阶段，可参考下图：



After we know about how to provide evidence for a clinical evaluation, let's have a look at when clinical evaluation will be needed in overseas competent authorities.

IN EU:

Clinical data is a must when confirm conformity to Annex I (section 1&3: characteristics and performances) and Annex I, section 6(side-effect and acceptability of benefit/risk ratio)

Clinical investigation: implantable devices and Class III may need to commence (unless it is duly justified to rely on existing clinical data)The implied meaning is that those don't have current clinical data to support will go through clinical investigation.

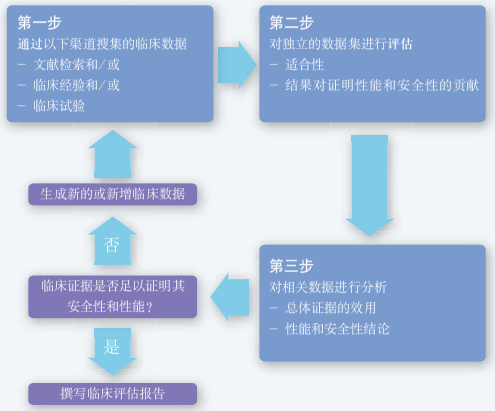
While clinical investigation needed:

Investigation Scope:

For pre-market approval

— to verify that, under normal conditions of use, the performance of the

Why clinical evaluation is important? It is because that the clinical evaluation is to demonstrated the device achieves its intended performance during normal conditions of use and that the known, and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of the intended performance, and that any claims made about the device's performance and safety (e.g. product labelling and instructions for use) are supported by suitable evidence. The clinical data shall be sufficient; it can follow a scheme as showed in below figure to demonstrate.



在我们了解如何提供临床评估的证据之后，让我们来了解一下国外相关部门对于临床数据或临床试验的具体要求概况。

欧洲：

在确定产品是否符合附录一第1、3章：特点和有效性与附录一第6章（风险相较于收益是否处于可接受范围）时的相关要求时，必须使用**临床数据**。

临床试验：植入式医疗器械和三类器械可能要求进行临床试验（除非依靠现有临床的数据足以证明其安全性和有效性）。其含义是，如果器械目前缺乏足够的临床数据支持其安全性有效性的说明，将需要进行临床试验。

如果器械需要临床试验，则：

试验目的

用于上市前审批的目的：

— 确认在正常使用条件下器械符合附件一第三章规定的有效性要求，并且

— 确定在正常使用条件下出现的所有非预期的副作用，并评估这些非预期副反应是否构成可能造成伤害的风险，并评估该风险相较于器械的预期有效性是否处于可接受范围。

申请对象

告知主管当局。并且伦理委员会的审批也是必不可少的。

申请程序

在通知主管当局60天之后，同时通过了伦理委员会的审批，即可开始临床试验，除非主管当局在规定期限内出于对公共健康或公共政策（审查范围包括伦理及临床方案）的考虑，作出不予进行试验的决定。在主管当局做出决定之后，公告机构会继续对试验方案等进行评估。

国外数据

如果试验根据GCP的规定开展，则可以认可在国外进行临床试验生成的数据。

美国：

在美国，由于510k采用实质等同原则，即新申请的器械必须证明其和市场上现有的器械是实质等同的，因此大多数510k候选器械不需

devices conform to those referred to in Section 3 of Annex I, and

— to determine any undesirable side-effects, under normal conditions of use, and assess whether they constitute risks when weighed against the intended performance of the device.

To whom to apply

Notify to Competent authority. The investigation shall also be approved by IRB.

Apply procedure

Notify CA then can start after 60 days unless CA notify him within the period of a decision to the contrary based on considerations of public health or public policy (review of ethics and plan). CA approves then NB assess.

Foreign data acceptance

Foreign data is accepted as long as the investigation was carried out according to GCP.

In US

In US as the 510k requires a substantial equivalence to existing device, most 510k candidates don't require clinical materials based on this reason. While PMA applies to devices with serious risk or have no prior device to compare to, this means they probably can't demonstrate safety with pre-clinical data or they can't find sufficient clinical data to prove the safety, in this light, most PMA is submitted with a clinical evaluation report, in which mostly contains clinical investigation data.

If a device needs clinical investigation then:

Investigation Scope

For pre-market approval

Must comply GCP(21 CFR 812, *Investigational Device Exemptions*, 21 CFR 50, *Protection of Human Subjects*, 21 CFR 56, *Institutional Review Boards*, 21 CFR 54, *Financial Disclosure by Clinical Investigators*, 21 CFR 820 Subpart C, *Design Controls of the Quality System Regulation*)

To whom to apply

FDA/IRB(institutional review board)

Apply procedure

Identify significant risk or non-significant risk device. If it is identified as significant risk, both FDA and IRB shall approve the investigation. If it is identified as non-significant risk, approval is only needed from IRB.

Foreign data acceptance

FDA permits the acceptance of foreign clinical studies in support of an application for marketing approval of a human drug, biological product, or device if certain conditions are met. Foreign studies performed under an investigational new drug application (IND) or investigational device exemption (IDE) must meet the same requirements of 21 CFR Part 312 or 21 CFR Part 812, respectively, that apply to U.S. studies conducted under an IND or IDE.

要提供临床资料（因为现有器械既然已经在市场上存在多年，其临床使用上的表现已经经过实践证明）。但对于通过申请PMA的途径，申请上市的器械来说，PMA途径范围内的器械为存在较高风险，或市场上不存在类似器械的产品，这意味着可能无法找到足够的现成的临床数据以证明其安全性。在此情况下，大多数PMA需要提交临床评估报告，并且常常需要到临床试验中去寻找现有文件中不足以提供的安全性和有效性方面的数据。

如果器械需要临床试验，则：

试验目的

用于上市前审批的目的：

必须符合GCP（21 CFR812 试验器械豁免、21 CFR50人体保护、21CFR56伦理审查委员会、 21CFR54临床试验人的财务公开以及21CFR820 C部分质量体系规范的设计控制）的规定。

申请对象

FDA和/或IRB （临床伦理审查委员会）

申请程序

根据器械是否属于高风险类别，临场试验的申请程序有所不同。如果确认器械具有高风险，则需要同时通过FDA与IRB审批才能进行该试验。如果器械属于非高风险器械，则只需要IRB审批通过即可。

外国数据认可

在满足相关要求的情况下，FDA允许接受国外临床试验来支持人用药品、生物制品或器械的上市审批申请。这些相关要求包括：国外试验，必须满足 21CFR 312条或者21CFR 812条的要求。对国外进行的临床试验，其要求和在美国国内进行的用于申请上市审批用临床试验的要求是一样的。

Notes: All Chinese information in Newsletter extracted from Newspapers and Internet.
备注：Newsletter中所有中文信息摘自报刊及网络。

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