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NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

Headline

NMPA Holds Meeting to Promote PIC/S Accession

On July 27, the Department of Drug Regulation of the NMPA holds a meeting in Kunming, Yunnan province to promote accession to the Pharmaceutical Inspection Co-operation Scheme(PIC/S). The meeting overviews NMPA current progress of applying for PIC/S accession since this year, analyzes the results and common issues of each provincial-level medical products administration based on their self-assessment on par with the requirements, circulates the comparative analysis between the domestic GMP and the PIC/S GMP Guide, further deploys tasks for the next phase and clarifies the working requirements.

The meeting invites experts from the Department of Health, Hong Kong SAR to explicitly introduce detailed conditions of application documents and specific procedures of on-site evaluation when Hong Kong SAR applying for PIC/S accession, as well as the current situation of drug regulatory system construction and drug inspection in Hong Kong SAR. Officials from the Center for Food and Drug Inspection (CFDI) of the NMPA and provincial-level medical products administrations introduced PIC/S Quality System Requirements for Pharmaceutical Inspectorates, PIC/S Risk-Based Inspection Planning and Guidance on Classification of GMP Deficiencies, Quality Risk Management (ICH Q9) guideline, and the construction of a professional and specialized inspector team based on their work experience. The meeting also invites experts to share the comparative study and implementation experience on the PIC/S annex of sterile medicinal products.

The meeting emphasized that provincial-level medical products administrations should enhance their political stance and fully recognize the significance of joining PIC/S in reinforcing the drug inspection capabilities and promoting the standardization and internationalization of drug regulation in China. The meeting requires all relevant institutions to focus on key tasks, strengthen work collaboration, and make every effort to prepare application documents; Each provincial-level medical products administration, in accordance with the deployment of the NMPA, should continuously improve the mechanism for drug inspection, persistently optimize the quality management system of drug inspection, take this opportunity to steadily promote the construction of the drug inspector team and enhance the modernization of drug regulation.

The head of the Department of Drug Regulation of the NMPA, the leaders of CFDI and China Center for Food and Drug International Exchange, and relevant responsible persons of NMPA special team for PIC/S accession attend the meeting. The heads of key provincial-level medical products administrations, and directors of manufacturing regulation divisions and heads of drug control institutions of provincial-level medical products administrations also attend the meeting.

(July 29,2023)

头条

国家药监局召开加入药品检查合作计划工作推进会

7月27日，国家药监局药品监管司在云南省昆明市召开加入药品检查合作计划（PIC/S）工作推进会。会议总结了今年以来申请加入PIC/S工作阶段性进展情况，分析了各省级药品监管部门对标开展自评估情况和存在的共性问题，通报了我国药品GMP与PIC/S药品GMP对比分析情况，部署了下一阶段重点任务，明确了工作要求。

会议邀请中国香港卫生署专家介绍了香港加入PIC/S申请资料准备的详细情况、接受现场评估的具体流程以及香港药品监管体系建设、药品检查工作等情况。来自国家药监局核查中心和省级药品监管部门的多位同志结合工作实际介绍了PIC/S关于药品检查质量体系要求、PIC/S基于风险制定检查计划和检查缺陷分级要求、药品质量风险管理指南（ICH-Q9）、职业化专业化检查员队伍建设等情况。会议还邀请了有关专家介绍PIC/S无菌药品附录的对比研究情况及实施体会。

会议强调，各省级药品监管部门要提高政治站位，充分认识加入PIC/S对提升我国药品检查能力、推进我国药品监管规范化和国际化的重要意义。会议要求，各有关单位要聚焦重点任务，加强工作协作，全力做好申请资料准备；各省级药品监管部门要按照国家药监局部署，持续完善药品检查有关制度，不断健全药品检查质量管理体系，并以此为契机，稳步推进药品检查员队伍建设，提升药品监管现代化水平。

国家药监局药品监管司主要负责人，核查中心、国际交流中心负责人以及国家药监局加入PIC/S专班有关负责同志参加会议，重点省份省级药品监管部门负责人以及各省级药品监管部门药品生产监管处室负责人、药品检查机构负责人参加会议。

(2023-07-29)

Published by
China Center for Food and Drug International Exchange

Qijiao Tiaojing Granule Approved for Marketing by China NMPA

Recently, the new traditional Chinese medicine (TCM) compound preparation Qijiao Tiaojing Granule of Hunan Anbang Pharmaceutical Co., Ltd. was approved for marketing by China NMPA.

The drug is composed of nine ingredients, including Radix Astragali, Colla Corii Asini, , Radix Codonopsis, and Radix Paeoniae Alba etc. It has the effect of nourishing Qi, replenishing blood, stopping bleeding, and regulating menstruation. It is indicated to treat prolonged menstrual periods caused by intrauterine device insertion with TCM syndrome differentiation of Qi and blood deficiency.

Multicenter, randomized, double-blinded, parallel gourp and positive TCM-controlled clinical trials showed that the recovery rate and improvement rate were 31.82% and 63.64% respectively in the experimental group, and 12.00% and 38.00% in the controlled group, demonstrating that the differences between groups are of statistical significance. The marketing of the drug provides new treatment option for patients.

(Dec 28,2022)

国家药监局批准中药新药芪胶调经颗粒上市

近日，国家药品监督管理局批准了湖南安邦制药股份有限公司申报的中药新复方制剂芪胶调经颗粒上市。该药品由黄芪、阿胶、党参、白芍等9味药组方，具有益气补血、止血调经功效，用于上环所致经期延长中医辨证属气血两虚证。

该药品开展了多中心、随机、双盲、已上市中药平行对照临床试验。临床试验研究结果显示，痊愈率、愈显率，试验组分别为31.82%、63.64%，对照组分别为12.00%、38.00%，组间比较，差异均有统计学意义。该药品上市将为临床相关疾病的患者提供新的治疗选择。

(2022-12-28)

Shenge Bushen Capsule Approved for Marketing by China NMPA

Recently, the Category 1.1 innovative traditional Chinese medicine (TCM) Shenge Bushen Capsule of Xinjiang Huachun Biological Pharmaceutical Co., Ltd was approved for marketing by China NMPA.

Randomized, double-blinded, parallel group, placebo-controlled and multicenter clinical trials were conducted on this drug. The results showed that the difference between the score of the primary efficacy endpoint HAMD-17 and the baseline demonstrating the efficacy in the experimental group was better than that in the placebo-controlled group.

The medicine which replenishing Qi, nourishing Yin and tonifying kidney, is indicated to treat mild to moderate depression with TCM syndrome differentiation of Qi and Yin deficiency, and kidney Qi deficiency. The marketing of this drug provides another treatment option for patients with depression.

(Dec 29,2022)

国家药监局批准中药创新药参葛补肾胶囊上市

近日，国家药品监督管理局批准了新疆华春生物药业股份有限公司申报的中药1.1类创新药参葛补肾胶囊上市。

该药品开展了随机、双盲、安慰剂平行对照的多中心临床试验，临床试验研究结果显示，主要疗效指标 HAMD -17评分与基线的差值，试验组疗效优于安慰剂组。

该药品益气，养阴，补肾，适用于轻、中度抑郁症中医辨证属气阴两虚、肾气不足证。该药品的上市为抑郁症患者提供了又一种治疗选择。

(2022-12-29)

TCM Compound Preparation Pipa Qingfei Granules Approved for Marketing by China NMPA

Recently, another traditional Chinese medicine (TCM) compound preparation Pipa Qingfei granules regulated as one of the ancient classic formulae (which is a category 3.1 innovative TCM) is approved for marketing through technical evaluation. The formula of this TCM is derived from the Yi Zong Jin Jian (Golden Mirror of Medicine) by Wu Qian etc. from Qing dynasty, and enlisted in the Directory of Ancient Classic Formulae of Traditional Chinese Medicine (the first directory). The marketing authorization holder of this TCM is Jilin Aodong Taonan Pharmaceutical Co., Ltd.

As recorded in Yi Zong Jin Jian, "this syndrome is caused by the blood heat in lung meridian. It usually generates pimples on face and nose that are shaped like millet bran, red and with swelling pain and broken out with white thick pus. As the course of disease developing, it becomes white, shaped like white millet bran. It is advisable to orally take Pipa Qingfei decoction." The Chinese patent medicine Pipa (Folium Eriobotryae) Qingfei (lung-clearing) decoction has the effects of clearing the heat of lung meridian and is indicated for acne by wind invading lung,

国家药监局批准按古代经典名方目录管理的中药复方制剂枇杷清肺颗粒上市

近日，又一个按古代经典名方目录管理的中药复方制剂（即中药3.1类新药）枇杷清肺颗粒通过技术审评，获批上市。该药品处方来源于清·吴谦等《医宗金鉴》，已列入《古代经典名方目录（第一批）》，药品上市许可持有人为吉林敖东洮南药业股份有限公司。

《医宗金鉴》记载："此证由肺经血热而成。每发于面鼻，起碎疙瘩，形如黍屑，色赤肿痛，破出白粉汁，日久皆成白屑，形如黍米白屑。宜内服枇杷清肺饮。"其成药制剂枇杷清肺颗粒，清肺经热，用于肺风酒刺，症见面

causing syndrome of pimples on face and nose, red and with swelling pain, broken out with thick pus or causing dry patches. The marketing of this TCM variety will be conducive to promoting the wider use of ancient classic formulae in clinical practice, enhancing the influence of TCM in clinical service and bringing more convenience to drug availability for patients.

(July 27,2023)

鼻疙瘩，红赤肿痛，破出粉汁或结屑等。该品种的上市将有利于促进古代经典名方在临床更广泛的使用，并有助于提升中医临床服务水平及患者用药的便捷性。

(2023-07-27)

Tafolecimab Injection Approved for Marketing by China NMPA

Recently, the Tafolecimab Injection (trade name: SINTBILO®) of Innovent Biologics (Suzhou) Co., Ltd. is approved by China NMPA. The indication is: for the treatment of adult patients with primary hypercholesterolemia (including heterozygous familial and non-familial hypercholesterolemia) and mixed dyslipidemia, who cannot achieve the recommended target of low density lipoprotein cholesterol (LDL-C) even after receiving moderate or high doses of statin therapy. It is used in combination with statins, or with statins and other lipid-lowering therapies.

The Tafolecimab Injection is a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. By inhibiting PCSK9, blocking the binding of plasma PCSK9 to low density lipoprotein receptor (LDLR), thereby preventing the endocytosis and degradation of LDLR, it increases the expression level and quantity of LDLR on the cell surface, increases LDLR reuptake of LDL-C, reduces circulating LDL-C levels and ultimately achieves the goal of reducing blood lipids. The marketing of this variety provides new treatment options for lipid-lowering treatment.

(Aug 16,2023)

国家药监局批准托莱西单抗注射液上市

近日，国家药品监督管理局批准信达生物制药（苏州）有限公司申报的托莱西单抗注射液（商品名：信必乐）上市。该药品适应症为：在控制饮食的基础上，与他汀类药物、或者与他汀类药物及其他降脂疗法联合用药，用于在接受中等剂量或中等剂量以上他汀类药物治疗，仍无法达到低密度脂蛋白胆固醇（LDL-C）目标的原发性高胆固醇血症（包括杂合子型家族性和非家族性高胆固醇血症）和混合型血脂异常的成人患者。

托莱西单抗注射液为前蛋白转化酶枯草溶菌素9（PCSK9）抑制剂。通过抑制PCSK9，阻断血浆PCSK9与低密度脂蛋白受体（LDLR）的结合，进而阻止LDLR的内吞和降解，增加细胞表面LDLR表达水平和数量，增加LDLR对低密度脂蛋白胆固醇（LDL-C）的重摄取，降低循环LDL-C水平，最终达到降低血脂的目的。该品种的上市为临床降脂治疗提供了新的治疗选择。

(2023-08-16)

Sunvozertinib Tablets Approved for Marketing by China NMPA

Recently, the Category 1 innovative drug Sunvozertinib Tablets (Chinese trade name: 舒沃哲) of Dizal (Jiangsu) Pharmaceutical Co., Ltd is approved by China NMPA. This drug is indicated for adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) who have experienced disease progression during or after platinum-containing chemotherapy, or are intolerant to platinum-containing chemotherapy, and have been confirmed to have an insertion mutation in the epidermal growth factor receptor (EGFR) exon 20 through testing.

Sunvozertinib is an EGFR tyrosine kinase inhibitor. The marketing of this drug provides a new treatment option for adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with EGFR 20 exon insertion mutations.

(Aug 23,2023)

国家药监局附条件批准舒沃替尼片上市

近日，国家药品监督管理局附条件批准迪哲（江苏）医药股份有限公司申报的1类创新药舒沃替尼片（商品名：舒沃哲）上市。该药适用于既往经含铂化疗治疗时或治疗后出现疾病进展，或不耐受含铂化疗，并且经检测确认存在表皮生长因子受体（EGFR）20号外显子插入突变的局部晚期或转移性非小细胞肺癌（NSCLC）的成人患者。

舒沃替尼是一种EGFR酪氨酸激酶抑制剂。该药品的上市为EGFR 20号外显子插入突变的局部晚期或转移性非小细胞肺癌（NSCLC）的成人患者提供了新的治疗选择。

(2023-08-23)

NMPA Announcement on Adopting ICH Guidelines Q12

To align the technical standards for drug registration with international standards, the NMPA has decided to adopt the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guidelines Q12: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management. The relevant items are hereby announced as follows:

1. The guidelines of Q12 provide a new approach and regulatory tool for post-approval changes for drugs. Applicants can conduct change management in accordance with the relevant regulations, provisions and guiding principles of change management in China, or use the new approach provided by Q12 when submitting marketing applications and/or supplementary applications. Before implementing Q12, applicants should fully evaluate whether they have the research and development foundation and implementation conditions applicable to the guidelines.

2. Starting from August 25, 2023, there will be a transition period of 24 months for the implementation of Q12. For drug registration applications during the transition period, if the applicant adopts Q12 for change management, please communicate and exchange with the Center for Drug Evaluation (CDE) of NMPA before submitting the drug registration application according to the relevant requirements of the management measures for communication and exchange of drug research and development and technical review (the NMPA CDE Notice No. 48 of 2020). Before the end of the 24 month transition period, it will be determined whether to extend the transition period based on the practical conditions during the transition period.

3. The Chinese and English versions of Q12 guidelines can be found at the CDE website. The CDE of NMPA is responsible for providing relevant technical guidance during the implementation of this Announcement.

National Medical Products Administration

August 25, 2023

(Aug 25,2023)

NMPA Announcement on Adopting ICH Guidelines S12

To align the technical standards for drug registration with international standards, the NMPA has decided upon deliberation to adopt the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guidelines S12: Nonclinical Biodistribution Considerations for Gene Therapy Products(hereinafter referred to as S12). The relevant items are hereby announced as follows:

Nonclinical studies starting from the issuance of this Announcement shall be applied to S12. The determination of the starting date of nonclinical studies shall be in accordance with the relevant provisions of the Good Laboratory Practice for drugs. The guidelines can be found at the website of the Center for Drug Evaluation(CDE) of the NMPA. The CDE of NMPA is

国家药监局关于适用《Q12：药品生命周期管理的技术和监管考虑》国际人用药品注册技术协调会指导原则的公告（2023年第108号）

为推动药品注册技术标准与国际接轨，经研究，国家药品监督管理局决定适用《Q12 药品生命周期管理的技术和监管考虑》国际人用药品注册技术协调会指导原则（以下简称Q12），现就有关事项公告如下：

一、Q12为药品上市后变更管理提供了新的实现方法和监管工具，申请人可以按照目前我国变更管理的相关法规规章和指导原则进行变更管理，也可以在提交上市申请和/或补充申请时采用Q12提供的新方法进行变更管理。申请人在实施Q12前，应充分评估是否具备适用该指导原则的研发基础和实施条件。

二、自2023年8月25日起24个月为Q12实施的过渡期。对于过渡期内的药品注册申请，如申请人采用Q12进行变更管理，请参照《药物研发与技术审评沟通交流管理办法》（国家药品监督管理局药品审评中心通告2020年第48号）相关要求，在提交药品注册申请前与国家药品监督管理局药品审评中心进行沟通交流。在24个月过渡期结束前，将根据过渡期实施情况，确定是否延长过渡期。

三、Q12指导原则的中英文版可在国家药品监督管理局药品审评中心网站查询。国家药品监督管理局药品审评中心负责做好本公告实施过程中的相关技术指导工作。

特此公告。

国家药监局

2023年8月25日

(2023-08-25)

国家药监局关于适用《S12：基因治疗产品非临床生物分布的考虑》国际人用药品注册技术协调会指导原则的公告（2023年第115号）

为推动药品注册技术标准与国际接轨，经研究，国家药品监督管理局决定适用《S12：基因治疗产品非临床生物分布的考虑》（以下简称 S12）国际人用药品注册技术协调会（ICH）指导原则。现就有关事项公告如下。

自本公告发布之日起开始的非临床研究适用S12指导原则。非临床研究起始日期的认定遵照《药物非临床研究质量管理规范》中相

responsible for providing relevant technical guidance during the implementation of this Announcement.

National Medical Products Administration

September 4, 2023

(Sep 5,2023)

关规定执行。

相关技术指导原则可在国家药品监督管理局药品审评中心网站查询。国家药品监督管理局药品审评中心负责做好本公告实施过程中的相关技术指导工作。

特此公告。

国家药监局

2023年9月4日

(2023-09-05)

Narlumosbart Injection Approved with Conditions for Marketing by China NMPA

Recently, the Narlumosbart Injection (Chinese trade name: 津立生) of Shanghai JMT Biological Technology Co. Ltd. is approved with conditions through the priority review and approval procedure by China NMPA. This drug is indicated for the treatment for adult patients with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity.

The Narlumosbart Injection is a recombinant human anti-receptor activator of NF-κB ligand (RANKL) monoclonal antibody. It can inhibit the activity of RANKL through specifically binding to RANKL on the cell membrane, thereby inhibiting its involvement in mediating osteolysis and tumor growth. The marketing of this drug provides a new treatment option for patients.

(Sep 6,2023)

国家药监局附条件批准纳鲁索拜单抗注射液上市

近日，国家药品监督管理局通过优先审评审批程序附条件批准上海津曼特生物科技有限公司申报的纳鲁索拜单抗注射液（商品名：津立生）上市。该药品用于治疗不可手术切除或手术切除可能导致严重功能障碍的骨巨细胞瘤成人患者。

纳鲁索拜单抗注射液为重组全人源抗核因子－κB受体活化因子配体（RANKL）单克隆抗体，通过与细胞表面的RANKL特异性结合，抑制RANKL活性，从而抑制其参与介导所引起的骨质溶解和肿瘤生长。该品种的上市为患者提供了新的治疗选择。

(2023-09-06)

NMPA Held 2023 ICH in China: Progress and Outlook Symposium

On September 12, NMPA held 2023 ICH in China: Progress and Outlook Symposium in Beijing, to make dialogue on development and cooperation with representatives from domestic and foreign industry associations. Huang Guo, Deputy Commissioner of China NMPA attended and addressed at the meeting.

Huang Guo stated that China is deeply involved in global drug safety governance and continuously deepening international cooperation. Through joining International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and becoming an ICH management committee member, NMPA has been actively learning from and sharing with international peers, accelerating the coordination and harmonization of regulatory rules, promoting mutual recognition of international regulation, and jointly enhancing the development of the global pharmaceutical industry.

He emphasized that the NMPA is willing to work together with all parties, adhere to the patient-focused concept, stick to the scientific, governance-by-law, international, and modernized path of development, continue to deepen drug regulatory reform and innovation, and accelerate the approval of drugs that are urgently needed on clinical side, so as to further expand external opening up and high-quality international cooperation, jointly foster a good ecosystem for high-quality development of the pharmaceutical industry, and protect and promote public health.

(Sep 13,2023)

国家药监局召开2023年ICH中国进程与展望座谈会

9月12日，国家药监局在京召开ICH中国进程与展望座谈会，与国内外行业协会代表共话发展与合作。国家药监局党组成员、副局长黄果出席会议并讲话。

黄果表示，中国国家药监部门深度参与全球药品安全治理，持续深化国际合作，加入并成为ICH（国际人用药品注册技术协调会）管委会成员，积极与国际同行互鉴互享，加快监管规则的协调与统一，推进国际监管互认，共促全球医药产业发展。

黄果强调，国家药监局愿与各方携手，坚持以患者为中心，坚持科学化、法治化、国际化、现代化的发展方向，持续深化药品监管改革创新，加快临床急需药品上市速度，推进更高水平的对外开放和更高质量的国际合作，共同营造医药产业高质量发展良好生态，保护和促进公众健康。

(2023-09-13)

Medical Devices

Artificial Lens Approved for Marketing

Recently, the innovative product Artificial Lens of Alcon Laboratories, Inc. is approved by China NMPA.

This product is a single-piece posterior chamber intraocular lens, of which the front surface center adopts a patented wavefront shaping structure. This product is suitable for adult patients with corneal astigmatism who have undergone extracapsular cataract extraction to remove the cataract lens. In the first phase, the product is implanted to correct vision by expanding the focal depth, which means expanding the visual range from long distance to functional close range while maintaining considerable distance vision, and therefore reducing patients' dependence on glasses. The marketing of this product will provide more options for clinical treatment.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(Apr 20, 2023)

Zirconium Niobium Alloy Femoral Head Approved for Marketing

Recently, the innovative product Zirconium Niobium Alloy Femoral Head of Suzhou MicroPort Orthopedics Medical Technology Co., Ltd. is approved by China NMPA.

The zirconium niobium alloy femoral head is used in conjunction with the components of hip joint prosthesis from the same series of this enterprise, applicable for total hip joint replacement. This product adopts zirconium niobium alloy that meets international standards (ASTM F2384), and forms a ceramic layer on the surface through gradient oxidation, which can reduce the wear rate of highly cross-linked polyethylene liner and reduce the revision rate of hip joint prostheses.

Compared with cobalt chromium alloy femoral heads commonly used in clinical practice, this product can reduce metal ion precipitation and joint surface wear; Compared with ceramic femoral heads, it can reduce the risks such as prosthesis fragmentation and joint noise. The marketing of this product will provide more options for clinical treatment.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(June 16, 2023)

Single-port Laparoscope Surgery System Approved for Marketing

Recently, the innovative product Single-port Laparoscope Surgery System of Beijing Surgerii Robotics Company Limited is approved by China NMPA.

This product is composed of a doctor's console, a patient's operating platform, a three-dimensional electronic abdominal endoscope, surgical instruments and accessories. It is applied for laparoscopy in urinary surgery. It is the first domestic single-port laparoscope surgery system filling the gap. The surgical instruments of this product adopt innovative technologies that are internationally pioneered and possess independent intellectual property rights, featuring with technological advantages such as wide range of motion, strong load capacity, and high reliability.

医疗器械

人工晶状体获批上市

近日，国家药品监督管理局经审查，批准了美国爱尔康公司生产的"人工晶状体"创新产品注册。

该产品为一件式后房人工晶状体，其前表面中心采用具有专利技术的波前塑形结构。该产品适用于存在角膜散光且经囊外白内障摘除术摘除白内障晶状体后的成人患者，一期植入该产品通过扩展焦点深度进行视力矫正，即在保持相当远视力的前提下，扩展从远距离至功能性近距离的视力范围，降低患者对眼镜的依赖。该产品上市将为临床治疗提供更多选择。

药品监督管理部门将加强该产品上市后监管，保护患者用械安全。

(2023-04-20)

锆铌合金股骨头获批上市

近日，国家药品监督管理局经审查，批准了苏州微创关节医疗科技有限公司生产的"锆铌合金股骨头"创新产品注册。

锆铌合金股骨头与该企业同系列髋关节假体组件配合使用，适用于全髋关节假体置换。该产品采用符合国际标准（ASTM F2384）的锆铌合金，经表面梯度氧化形成类陶瓷层，可以减少高交联聚乙烯髋臼内衬磨损，降低髋关节假体翻修率。

与目前临床常用类似预期用途的钴铬合金股骨头产品相比，该产品可减少金属离子析出、降低关节面磨损；与陶瓷股骨头产品相比，可降低假体碎裂、关节异响等风险。该产品上市将为临床治疗提供更多选择。

药品监督管理部门将加强该产品上市后监管，保护患者用械安全。

(2023-06-16)

腹腔内窥镜单孔手术系统获批上市

近日，国家药品监督管理局批准了北京术锐机器人股份有限公司生产的"腹腔内窥镜单孔手术系统"创新产品注册申请。

该产品由医生控制台、患者手术平台、三维电子腹腔内窥镜、手术器械及附件组成，用于泌尿外科腹腔镜手术操作，为国内首个内窥镜单孔手术系统，有效填补了国内空白。该产品中的手术器械采用国际首创、拥有自主知识产权的创新技术，具有运动范围广、负载

This product performs surgery through a single port to reduce the number of abdominal ports for patients. The endoscope and surgical instruments have multiple active degrees of freedom, which enable the surgical operations to be completed through the movement of the surgical instruments within the patient's abdominal cavity. The external positioning arm remains stationary during remote operation, which avoids the risk of collision during surgery. The unique operating system of this product help doctors to control the surgery, to improve operation accuracy and reduce operation wounds.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(June 20, 2023)

能力强和可靠性高等技术优势。

该产品以单孔方式实施手术，减少患者腹部开孔数量。内窥镜及手术器械有多个主动自由度，仅通过手术器械在患者腹腔内的运动即可完成手术操作。体外定位臂在遥操作过程中保持静止，避免了术中相互碰撞的风险。医生利用该产品特有操控系统进行控制，可提高操作精细化水平，减少手术创伤。

药品监督管理部门将加强该产品上市后监管，保护患者用械安全。

(2023-06-20)

Venous Stent System Approved for Marketing

Recently, the innovative product Venous Stent System of Suzhou Innomed Medical Device Co., Ltd. is approved by China NMPA.

The venous stent system consists of a self-expanding nickel titanium alloy stent and a delivery system. The self-expanding stent is woven from nickel titanium wire, featured with flexibility, bending resistance, and fatigue resistance. This product has a unique self compensative structure after release to ensures table and accurate release shape of venous stents during surgery. It also has a recyclable function, which can withdraw 90% of the stent length back to the delivery system before it is fully pushed out, which enables reposition and release for one more time, to solve abnormal issues during release and improve product safety.

This product is intended to be applied in the iliofemoral vein for the treatment of non-thrombotic iliac vein compression syndrome and post deep vein thrombosis syndrome. The marketing of this product will provide more options for clinical treatment.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(July 31, 2023)

静脉支架系统获批上市

近日，国家药品监督管理局经审查，批准了苏州茵络医疗器械有限公司生产的"静脉支架系统"创新产品注册。

静脉支架系统由自膨式镍钛合金支架和输送系统组成。自膨支架由镍钛丝编织而成，具有柔顺性、抗折性和耐疲劳性。该产品带有独特的释放自补偿结构，保证在手术过程中静脉支架释放形态稳定精准；还具有可回收功能，可在静脉支架没有被完全推出输送系统的情况下，将90%支架长度重新回收至输送系统内，并重新定位释放一次，解决释放中的异常问题，提高产品安全性。

该产品预期在髂股静脉内使用，用于治疗非血栓性髂静脉压迫综合征和深静脉血栓形成后综合征。该产品上市将为临床治疗提供更多选择。

药品监督管理部门将加强该产品上市后监管，保护患者用械安全。

(2023-07-31)

Medical Electronic Linear Accelerator Approved for Marketing

Recently, the innovative product Medical Electronic Linear Accelerator of Xian OUR UNITED Corp. is approved by China NMPA.

This product is composed of a frame, beam generation module, beam shaping module, treatment bed, image guidance system, and control system, which is the first of its kind domestically. It is applied to provide image-guided 3D conformal radiotherapy, intensity-modulated radiotherapy, volume-modulated radiotherapy, and stereotactic body radiotherapy for solid tumors and lesions suitable for radiotherapy in the human body. This product applies a circular frame with conductive slip rings, which can shorten treatment time and improve treatment efficiency for clinically complex patients who require multi-arc continuous radiotherapy.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(Aug 1, 2023)

医用电子直线加速器获批上市

近日，国家药品监督管理局批准了西安大医集团股份有限公司生产的医用电子直线加速器创新产品注册申请。

该产品由机架、束流产生模块、射野成形模块、治疗床、图像引导系统、控制系统组成，属国内首创，用于对人体适合接受放射治疗的实体肿瘤和病变提供图像引导下的三维适形放射治疗、适形调强放射治疗、容积调强放射治疗以及体部立体定向放射治疗。该产品应用带导电滑环的环形机架，对于临床上较复杂的需要多弧连续治疗的患者，可缩短治疗时间，提高治疗效率。

药品监督管理部门将加强该产品上市后监管，保护患者用械安全。

(2023-08-01)

Rigid Scleral Contact Lens Approved for Marketing

Recently, the innovative product Rigid Scleral Contact Lens of Shanghai Aikangte Medical Technology Co., Ltd. is approved by China NMPA.

This product is a daily-wear and large-diameter rigid scleral contact lens (commonly known as "scleral lens"). The lens material is hexafocon A, colored in ice blue. This product is composed of four arc segments: optical zone, peripheral central clearance zone, limbus corneal zone and scleral landing zone. During clinical testing, parameter adjustments can be made to each arc segment to obtain a more ideal thickness of the microscopic fluid, improving the patient's visual quality while also protecting corneal tissue. This product innovatively adopts a double sagittal deep asymmetric design, which can better match the asymmetric sclera. The scleral landing area is designed with a reverse curved surface, providing patients with a more comfortable wearing experience.

This product is suitable for patients with refractive errors or for those who have +25.00D to -25.00D with corneal regular astigmatism less than 5.00D to correct irregular astigmatism. The marketing of this product will provide more options for clinical treatment.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(Aug 3, 2023)

硬性巩膜接触镜获批上市

近日，国家药品监督管理局经审查，批准了上海艾康特医疗科技有限公司生产的"硬性巩膜接触镜"创新产品注册。

该产品为日戴型硬性巩膜接触镜，是一种大直径的硬性接触镜（俗称"巩膜镜"），镜片材料为氟硅丙烯酸酯（hexafocon A），着冰蓝色。该产品由光学区（OZ）、中周区（PCCZ）、角膜缘区（LCZ）和巩膜着陆区（SLZ）四个弧段组成，在临床验配时可通过对各弧段进行参数调整获得更理想的镜下液厚度，改善患者视觉质量的同时还可保护角膜组织。该产品创新性采用双矢深非对称设计，能够更好地匹配不对称巩膜 巩膜着陆区为反转弧面设计，患者佩戴体验更舒适。

该产品适用于矫正不规则散光，或同时合并有+25.00D至-25.00D，角膜规则散光小于5.00D的屈光不正患者。该产品上市将为临床治疗提供更多选择。

药品监督管理部门将加强该产品上市后监管，保护患者用械安全。（2023-08-03）

Hip Replacement Navigation Positioning System Approved for Marketing

Recently, the innovative product Hip Replacement Navigation Positioning System of Hangzhou Lancet Robotics company is approved by China NMPA.

This product is composed of a robotic arm trolley, a main console trolley, an optical tracking trolley, a foot switch, a medical electric bone drill, and surgical tools. It can be used in conjunction with validated hip joint prostheses and surgical tools to assist doctors in completing tasks such as acetabulum grinding, femoral osteotomy, and hip joint prosthetic installation during hip replacement surgery. This product is with independent intellectual property rights, of which the performance indicators are on par with international standards of the same devices.

Compared with conventional hip replacement surgery, surgery with this product can improve surgical positioning accuracy, reduce adverse events and complications, and reduce radiation damage to doctors and patients caused by X-rays.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(Aug 11, 2023)

髋关节置换手术导航定位系统获批上市

近日，国家药品监督管理局经审查，批准了杭州柳叶刀机器人有限公司生产的"髋关节置换手术导航定位系统"创新产品注册申请。

该产品由机械臂台车、主控操作台车、光学追踪台车、脚踏开关、医用电动骨钻和手术工具组成，与经验证的髋关节假体和手术工具联合使用，可以在髋关节置换手术中辅助医生完成髋臼打磨、股骨截骨、髋关节假体安装等工作。该产品具有自主知识产权，各项性能指标达到国际同品种器械水平。

与传统人工髋关节置换术相比，该产品可以提升手术定位精度，减轻不良事件和并发症的发生概率，降低X射线对医生和患者的辐射损伤。

药品监督管理部门将加强该产品上市后监管，保护患者用械安全。（2023-08-11）

Notes: • All the Chinese information in the Newsletter is from newspapers and the Internet. All English articles are translated from the Chinese version. In case of any discrepancy, the Chinese version shall prevail.
• For e-paper of the Newsletter, please visit http://www.ccfdie.org

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