2024 Volume 6

NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

Headline

NMPA Announcement on Issuing the Interim Provisions on the Management of Designated Domestic Responsible Persons by Overseas Marketing Authorization Holders (No. 137, 2024)

To implement the Drug Administration Law of the People's Republic of China and the Vaccine Administration Law of the People's Republic of China, and to strengthen the management of overseas marketing authorization holders (MAHs), the National Medical Products Administration (NMPA) has formulated the Interim Provisions on the Management of Designated Domestic Responsible Persons by Overseas Marketing Authorization Holders. These provisions are hereby issued and will come into effect from July 1, 2025.

Additionally, to ensure the effective implementation of the Interim Provisions on the Management of Designated Domestic Responsible Persons by Overseas Marketing Authorization Holders, the NMPA has developed relevant modules in the National Pharmaceutical Business Application System, which will be officially launched on November 14, 2024.

It is hereby announced.

National Medical Products Administration

November 13, 2024

(November 14, 2024)

头条

国家药监局关于发布《境外药品上市许可持有人指定境内责任人管理暂行规定》的公告（2024年第137号）

为贯彻落实《中华人民共和国药品管理法》《中华人民共和国疫苗管理法》，加强境外药品上市许可持有人管理，国家药监局制定了《境外药品上市许可持有人指定境内责任人管理暂行规定》，现予发布，自2025年7月1日起实施。

同时，为保障《境外药品上市许可持有人指定境内责任人管理暂行规定》的落地实施，国家药监局建设了国家药品业务应用系统相关模块，于2024年11月14日正式启用。

特此公告。

国家药监局

2024年11月13日

（2024-11-14）

Drugs

Ebronucimab Injection Approved for Marketing by China NMPA

Recently, the Ebronucimab Injection (trade name: 伊喜宁) of Kangrong Dongfang (Guangdong) Pharmaceutical Co., Ltd. is approved for marketing 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.

Ebronucimab is a fully human monoclonal IgG1 antibody targeting the preprotein convertase subtilisin/kexin type 9 (PCSK9), which blocks the binding of PCSK9 to the low-density lipoprotein receptor (LDLR) by specifically binding to PCSK9, preventing PCSK9-mediated degradation of the LDLR, and increasing the number of LDLRs on the surface of the cells, thereby reducing serum LDL-C levels. The marketing of this product provides a new treatment option for lipid-lowering treatment.

(September 30, 2024)

药品

国家药监局批准伊努西单抗注射液上市

近日，国家药品监督管理局批准康融东方（广东）医药有限公司申报的伊努西单抗注射液（商品名：伊喜宁）上市。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以上剂量他汀类药物治疗后，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。

伊努西单抗是一种作用靶点为前蛋白转化酶枯草溶菌素9（PCSK9）的全人源单克隆IgG1抗体，通过特异性结合PCSK9，阻断PCSK9与低密度脂蛋白受体（LDLR）结合，阻止PCSK9介导的LDLR降解，提高细胞表面LDLR数目，进而降低血清中LDL-C水平。该品种的上市为临床降脂治疗提供了新的治疗选择。

（2024-09-30）

Published by
China Center for Food and Drug International Exchange

Iparomlimab and Tuvonralimab Injection Approved with Conditions for Marketing by China NMPA

Recently, the Iparomlimab and Tuvonralimab Injection (trade name: 齐倍安) of Qilu Pharmaceuticals Co., Ltd. is approved for marketing with conditions by China NMPA. It is indicated for the treatment of recurrent or refractory cervix carcinoma patients who progressed on or after platinum-based chemotherapy.

Iparomlimab and Tuvonralimab Injection is a bifunctional combination antibody consisting of Iparomlimab, which targets human programmed death receptor-1 (PD-1), and Tuvonralimab, which targets human cytotoxic T-lymphocyte-associated protein-4 (CTLA-4). It specifically binds to PD-1 and CTLA-4 receptors, blocking the PD-1/PD-L1 and CTLA-4/B7-1/B7-2 immune checkpoint signaling pathways. This dual blockade releases the inhibition on T-lymphocytes, promoting tumor-specific T-cell immune activation and thereby exerting an anti-tumor effect. The marketing of this product provides a new treatment option for patients with recurrent or refractory cervix carcinoma.

(September 30, 2024)

国家药监局附条件批准艾帕洛利托沃瑞利单抗注射液上市

近日，国家药品监督管理局附条件批准齐鲁制药有限公司申报的艾帕洛利托沃瑞利单抗注射液（商品名：齐倍安）上市，用于既往接受含铂化疗治疗失败的复发或转移性宫颈癌患者的治疗。

艾帕洛利托沃瑞利单抗注射液是由靶向人程序性死亡受体-1（PD-1）的艾帕洛利单抗与靶向人细胞毒性T淋巴细胞相关蛋白-4（CTLA-4）的托沃瑞利单抗组成的双功能组合抗体。可特异性结合PD-1和CTLA-4受体，阻断PD-1与PD-L1以及CTLA-4与B7-1/B7-2两条免疫检查点信号通路，同时解除两条通路对T淋巴细胞的抑制作用，促进肿瘤特异性的T细胞免疫活化，进而发挥抗肿瘤作用。该品种的上市为复发或转移性宫颈癌患者提供了新的治疗选择。

（2024-09-30）

Ongericimab Injection Approved for Marketing by China NMPA

Recently, the Ongericimab Injection (trade name: 君适达/Junshida) of Shanghai Junshi Biosciences Co., Ltd. is approved for marketing by China NMPA. The indication is: for the treatment of adult patients with primary hypercholesterolemia (non-familial) 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 Ezetimibe.

Ongericimab is a fully human monoclonal IgG1 antibody targeting the preprotein convertase subtilisin/kexin type 9 (PCSK9), which blocks the binding of PCSK9 to the low-density lipoprotein receptor (LDLR) by specifically binding to PCSK9, preventing PCSK9-mediated degradation of the LDLR, and increasing the number of LDLRs on the surface of the cells, thereby reducing serum LDL-C levels. The marketing of this product provides a new treatment option for lipid-lowering treatment.

(October 11, 2024)

国家药监局批准昂戈瑞西单抗注射液上市

近日，国家药品监督管理局批准上海君实生物医药科技股份有限公司申报的昂戈瑞西单抗注射液（商品名：君适达）上市。适应症为：在控制饮食的基础上，与他汀类药物、或者与他汀类药物和依折麦布联合用药，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（非家族性）和混合型血脂异常的成人患者。

昂戈瑞西单抗是一种作用靶点为前蛋白转化酶枯草溶菌素9（PCSK9）的全人源单克隆IgG1抗体，通过特异性结合PCSK9，阻断PCSK9与低密度脂蛋白受体（LDLR）结合，阻止PCSK9介导的LDLR降解，提高细胞表面LDLR数目，进而降低血清中LDL-C水平。该品种的上市为临床降脂治疗提供了新的治疗选择。

（2024-10-11）

Pradefovir Mesylate Tablets Approved for Marketing by China NMPA

Recently, the Class 1 innovative drug Pradefovir Mesylate Tablets (trade name: 新舒沐) of Xi'an Gelan Xintong Pharmaceutical Co., Ltd. is approved for marketing by China NMPA. This drug is indicated for the treatment of adult patients with chronic hepatitis B, providing a new treatment option for patients.

(October 28, 2024)

国家药监局批准甲磺酸普雷福韦片上市

近日，国家药品监督管理局批准西安葛蓝新通制药有限公司申报的1类创新药甲磺酸普雷福韦片（商品名：新舒沐）上市，该药品适用于治疗成人慢性乙型肝炎，为患者提供了新的治疗选择。

（2024-10-28）

NMPA Announcement on the Applicability of ICH Guideline M12: Drug Interaction Studies and Its Q&A Document (No. 130, 2024)

To keep pace with the international technical standards for drug registration, NMPA has decided after research to apply ICH Guideline M12: Drug Interaction Studies and its Q&A document (hereinafter referred to as the M12 Guidelines and its Q&A document). The relevant issues are hereby announced as follows:

1. The M12 Guidelines and its Q&A document will apply to all relevant studies starting from October 29, 2024 (based on the time point of the trial record).

2. The relevant technical guidelines may be accessed on the website of the Center for Drug Evaluation of NMPA. The Center for Drug Evaluation of NMPA shall be responsible for relevant technical guidance during the implementation of this Announcement.

It is hereby announced.

National Medical Products Administration

October 29, 2024

(November 1, 2024)

国家药监局关于适用《M12：药物相互作用研究》国际人用药品注册技术协调会指导原则及问答文件的公告（2024年第130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《M12：药物相互作用研究》国际人用药品注册技术协调会指导原则及问答文件（以下简称M12指导原则及问答文件）。现将有关事项公告如下：

一、自2024年10月29日起开始的相关研究（以试验记录时间点为准），均适用M12指导原则及问答文件。

二、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

2024年10月29日

（2024-11-01）

NMPA Announcement on the Applicability of ICH Guideline E11A: Pediatric Extrapolation (No. 139, 2024)

To keep pace with the international technical standards for drug registration, NMPA has decided after research to apply ICH Guideline E11A: Pediatric Extrapolation (hereinafter referred to as the E11A Guidelines). The relevant issues are hereby announced as follows:

1. The E11A Guidelines will apply to all relevant studies starting from November 18, 2024 (based on the time point of the trial record).

2. The relevant technical guidelines may be accessed on the website of the Center for Drug Evaluation of NMPA. The Center for Drug Evaluation of NMPA shall be responsible for relevant technical guidance during the implementation of this Announcement.

It is hereby announced.

National Medical Products Administration

November 18, 2024

(November 19, 2024)

国家药监局关于适用《E11A：儿科外推》国际人用药品注册技术协调会指导原则的公告（2024年第139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《E11A：儿科外推》国际人用药品注册技术协调会指导原则（以下简称E11A指导原则）。现将有关事项公告如下：

一、自2024年11月18日起开始的相关研究（以试验记录时间点为准），均适用E11A指导原则。

二、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

2024年11月18日

（2024-11-19）

Garsorasib Tablets Approved with Conditions for Marketing by China NMPA

Recently, the Class 1 innovative drug Garsorasib Tablets (trade name: 安方宁) of Shanghai Chia-tai Tianqing Pharmaceutical Technology Development Co. Ltd. is approved

国家药监局附条件批准格索雷塞片上市

近日，国家药品监督管理局通过优先审评

with conditions for marketing through the priority review and approval procedure by NMPA in China. This drug is indicated for adult patients with advanced non-small cell lung cancer (NSCLC) carrying the Kirsten rat sarcoma viral oncogene (KRAS) G12C mutation who have received at least one systemic treatment, providing a new treatment option for patients.

(November 8, 2024)

审批程序附条件批准上海正大天晴医药科技开发有限公司申报的1类创新药格索雷塞片（商品名：安方宁）上市，该药适用于治疗至少接受过一种系统性治疗的鼠类肉瘤病毒癌基因（KRAS）G12C突变型的晚期非小细胞肺癌（NSCLC）成人患者，为患者提供新的治疗选择。

（2024-11-08）

Zorifertinib Hydrochloride Tablets Approved for Marketing by China NMPA

Recently, the Class 1 innovative drug Zorifertinib Hydrochloride Tablets (trade name: 泽瑞尼) of Alpha Biopharma (Jiangsu) Co., Ltd. is approved for marketing by China NMPA. This drug is indicated for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 (L858R) substitution mutation with central nervous system (CNS) metastases, providing a new treatment option for patients.

(November 20, 2024)

国家药监局批准盐酸佐利替尼片上市

近日，国家药品监督管理局批准江苏晨泰医药科技有限公司申报的1类创新药盐酸佐利替尼片（商品名：泽瑞尼）上市，该药适用于具有表皮生长因子受体（EGFR）19号外显子缺失或外显子21（L858R）置换突变，并伴中枢神经系统（CNS）转移的局部晚期或转移性非小细胞肺癌（NSCLC）成人患者的一线治疗，为患者提供新的治疗选择。

（2024-11-20）

Medical device

Renatus® Transcatheter Aortic Valve System Approved for Marketing

Recently, the innovative product "Renatus® Transcatheter Aortic Valve System" of Beijing Balance Medical Technology Co., Ltd. is approved by China NMPA.

This product consists of a bioprosthetic valve, a delivery device, a balloon dilatation catheter, a catheter sheath kit, a crimping device, and an inflation pump. The product features a balloon-expandable stent structure. It is indicated for patients with symptomatic, calcified, severe degenerative aortic valve stenosis who are evaluated by a heart team and deemed unsuitable for conventional surgical valve replacement, and who are 70 years of age or older. Under the guidance of medical imaging equipment, the bioprosthetic valve can be implanted through either a long or short delivery system, depending on the patient's specific access route, into the aortic annulus, replacing the diseased aortic valve and improving the stenosis at the affected site, thereby enhancing cardiac function and meeting the clinical needs of different access routes.

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

(August 22, 2024)

医疗器械

经导管主动脉瓣系统获批上市

近日，国家药品监督管理局批准了北京佰仁医疗科技股份有限公司"经导管主动脉瓣系统"创新产品注册申请。

该产品由生物瓣膜、输送器、球囊扩张导管、导管鞘套件、压握器、充压泵组成。采用球囊扩张式瓣架结构，适用于经心脏团队结合评分系统评估后认为患有有症状的、钙化的、重度退行性自体主动脉瓣狭窄，不适合接受常规外科手术置换瓣膜、年龄大于等于70岁的患者。在医学影像设备监护下，可选择性通过长、短两款输送系统经由不同入路将生物瓣膜植入到人体主动脉瓣环处，代替原有的病变主动脉瓣膜，改善病变部位狭窄，改善心功能，满足不同入路患者临床需求。

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。

（2024-08-22）

JETSTREAM™ PVCN100 Console and JETSTREAM™ Over-The-Wire Atherectomy Catheter Approved for Marketing

Recently, the two innovative products "JETSTREAM™ PVCN100 Console" and "JETSTREAM™ Over-The-Wire Atherectomy Catheter" of Boston Scientific

血管斑块旋切控制装置和一次性使用外周血管斑块旋切导管获批上市

近日，国家药品监督管理局批准了波士顿科学公司"血管斑块旋切控制装置"和"一次性

Corporation are approved by China NMPA.

The JETSTREAM™ PVCN100 Console consists of a main unit and a power cord. The JETSTREAM™ Over-The-Wire Atherectomy Catheter consists of an electrical catheter, an aspiration port, and a removable activation handle. These two products are used in combination for atherectomy pre-treatment of primary lesions in the femoropopliteal arteries. Compared with traditional atherectomy devices, this product adopts the innovative design of rotary excision combined with active suction, which realizes the functions of plaque excision and active suction-perfusion, providing more effective atherectomy efficacy while discharging plaque particles out of the body through the suction system, reducing the occurrence of adverse events such as distal embolization.

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

(August 28, 2024)

使用外周血管斑块旋切导管”两个创新产品注册申请。

血管斑块旋切控制装置由主机和电源线组成。一次性使用外周血管斑块旋切导管由电动导管、空间分离舱和可拆卸激活手柄组成。上述两个产品配套使用，用于股腘动脉原发性病变的经皮腔内斑块旋切预处理治疗。

与传统斑块切除器械相比，该产品采用旋切结合主动抽吸的创新设计，实现了斑块切除及主动抽吸-灌注功能，在提供更有效的斑块切除疗效的同时，将斑块颗粒通过抽吸系统排出体外，减少远端栓塞等不良事件的发生。

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。

（2024-08-28）

Lumipulse® G HBsAg-Quant Approved for Marketing

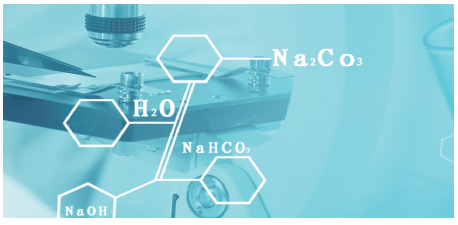
Recently, the innovative product “Lumipulse® G HBsAg-Quant” of Fujirebio Inc. is approved by China NMPA.

The Lumipulse® G HBsAg-Quant consists of antibody-conjugated particles, enzyme-labeled antibodies, and sample processing solution. It is used for the qualitative and quantitative in vitro detection of Hepatitis B Surface Antigen (HBsAg) in human serum or plasma.

Compared with similar products on the market, this product offers higher sensitivity, enabling the detection of HBsAg even at low concentrations in the early stages of Hepatitis B virus infection, thus facilitating early diagnosis and treatment.

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

(September 3, 2024)



乙型肝炎病毒表面抗原(HBsAg)检测试剂盒获批上市

近日，国家药品监督管理局批准了富士瑞必欧株式会社“乙型肝炎病毒表面抗原（HBsAg）检测试剂盒（化学发光法）”创新产品注册申请。

乙型肝炎病毒表面抗原(HBsAg)检测试剂盒由抗体结合粒子、酶标记抗体、样本处理液组成，用于体外定性和定量检测人血清或血浆中的乙型肝炎病毒表面抗原(HBsAg)。

与已上市同类产品相比，该产品具有较高灵敏度，能够在乙型肝炎病毒感染者感染初期，体内血液中乙肝病毒表面抗原浓度较低时检测出相应抗原，实现早诊断、早治疗。

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。

（2024-09-03）

Navigational Positioning Microwave Ablation System Approved for Marketing

Recently, the innovative product “Navigational Positioning Microwave Ablation System” of True Health (Beijing) Medical Technology Co., Ltd. is approved by China NMPA.

The Navigational Positioning Microwave Ablation System consists of a main control trolley (with robotic arms and a foot switch), a microwave therapy trolley (with an optical tracking module and a foot switch), navigation and positioning tools, microwave transmission lines, single-use microwave ablation needles, and single-use temperature monitoring needles. This product allows for preoperative needle planning based on CT images and intraoperative guidance for percutaneous puncture procedures, specifically for microwave ablation of solid liver tumors in adults.

Compared with traditional microwave ablation devices, this product innovatively integrates navigation and positioning technology, respiratory tracking technology, and microwave ablation technology, which is the first of its kind in the world. It significantly

导航定位微波消融系统获批上市

近日，国家药品监督管理局批准了真健康（珠海）医疗科技有限公司“导航定位微波消融系统”创新产品注册申请。

导航定位微波消融系统由主控台车（含机械臂、脚踏开关）、微波治疗台车（含光学跟踪模块、脚踏开关）、导航定位工具、微波传输线、一次性使用微波消融针及一次性使用测温针组成。该产品可在术前基于CT图像制定进针计划，术中引导微波消融针进行经皮穿刺手术，用于成人肝脏实体肿瘤的微波消融。

与传统微波消融设备相比，该产品创新性地融合了导航定位技术、呼吸跟踪技术和微波消融技术，为国际首创，有效提高临床微波消

improves the accuracy of microwave needle placement, target lesion ablation, and the efficiency and success rate of ablation procedures, while reducing the reliance on the operator's experience in puncture and ablation planning, thereby enhancing the effectiveness and safety of the treatment.

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

(September 3, 2024)

融针置针、病灶靶区消融的精准度以及消融手术效率和成功率，降低对医生穿刺、消融规划经验的要求，提高穿刺消融治疗的有效性和安全性。

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。

（2024-09-03）

PulseSelect™ Pulsed Field Ablation (PFA) Generator and PulseSelect™ Pulsed Field Ablation (PFA) Loop Catheter Approved for Marketing

Recently, the two innovative products "PulseSelect™ Pulsed Field Ablation (PFA) Generator" and "PulseSelect™ Pulsed Field Ablation (PFA) Loop Catheter" of Medtronic, Inc. are approved by China NMPA.

The PulseSelect™ Pulsed Field Ablation (PFA) Generator consists of a generator, a controller (optional), a foot switch (optional), an EGM cable, and a disposable catheter interface cable. The PulseSelect™ Pulsed Field Ablation (PFA) Loop Catheter consists of an electrode, a body and a handle.

The above two products are used in conjunction for the treatment of drug-refractory, recurrent, symptomatic paroxysmal atrial fibrillation or drug-refractory, recurrent, symptomatic persistent atrial fibrillation (with episodes lasting less than 1 year) by utilizing the principle of the non-thermal effect of a pulsed electric field. Compared with conventional radiofrequency ablation and cryoablation products, this product enables selective destruction of myocardial tissue and avoids the risk of surrounding tissue damage due to temperature transfer.

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

(September 10, 2024)

心脏脉冲电场消融仪和一次性使用心脏脉冲电场消融导管获批上市

近日，国家药品监督管理局批准了美敦力公司"心脏脉冲电场消融仪"和"一次性使用心脏脉冲电场消融导管"两个创新产品注册申请。

心脏脉冲电场消融仪由发生器、控制器（可选）、脚踏开关（可选）、EGM线缆、一次性使用导管接口线缆组成。一次性使用心脏脉冲电场消融导管由电极、管身和手柄组成。

上述两个产品配套使用，利用脉冲电场的非热效应原理，治疗药物难治性、复发性、症状性阵发性房颤或药物难治性、复发性、症状性持续性房颤（发作持续时间小于1年）。与传统的射频消融及冷冻消融产品相比，该产品可实现对心肌组织的选择性破坏，避免温度传递导致的周围组织损伤风险。

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。

（2024-08-06）

CT Angiography Image-aided Detection Software for Intracranial Aneurysms Approved for Marketing

Recently, the innovative product "CT Angiography Image-aided Detection Software for Intracranial Aneurysms" of Shanghai United Imaging Healthcare Co., Ltd. is approved by China NMPA.

This product consists of software installation programs and authorization files. The software function module includes browser and server ends, used for displaying, processing, measuring, and analyzing CT angiography images of the head and neck arteries, and assisting in the detection of intracranial aneurysms of 3 mm and above.

This product adopts deep learning-based head and neck vessel segmentation technology and multi-scale aneurysm detection technology, which effectively improves the diagnostic accuracy and efficiency of intracranial aneurysms, and is of great significance in improving the survival rate of patients.

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

(September 25, 2024)

颅内动脉瘤CT血管造影图像辅助检测软件获批上市

近日，国家药品监督管理局批准了上海联影智能医疗科技有限公司的"颅内动脉瘤CT血管造影图像辅助检测软件"创新产品注册申请。

该产品由软件安装程序和授权文件组成，功能模块包括浏览器端、服务器端，用于头颈动脉CT血管造影图像的显示、处理、测量和分析，可对颅内3mm及以上动脉瘤进行辅助检测。

该产品采用基于深度学习的头颈血管分割分段技术和多尺度动脉瘤检测技术，有效提高了颅内动脉瘤的诊断准确性和效率，对提升患者生存率具有重要意义。

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。

（2024-09-25）

Carbon Ion Therapy System Approved for Marketing

Recently, the product “Carbon Ion Therapy System” produced by Lanzhou Ion Therapy Co. Ltd. is approved by China NMPA.

The approved product will be put into clinical use at Economic and Technological Development Zone Branch, Renmin Hospital of Wuhan University. Compared with previously approved products, all treatment rooms in this system are equipped with modulated scanning mode, which further enhances treatment efficiency and precision. Some treatment rooms are also configured with a sliding rail CT image guidance system, improving image quality and positioning accuracy, thus better meeting the needs of patients with malignant solid tumors.

In recent years, the NMPA has continuously deepened its review and approval reforms, supporting innovation in the medical device industry and meeting the public's demand for high-end medical devices. Previously, the domestically produced "Carbon Ion Therapy System" approved by the NMPA has been used to treat over 1,500 patients, with excellent outcomes.

Moving forward, the NMPA will continue to implement specific measures in line with the reform deployments of the Central Committee of the Communist Party of China, supporting the high-quality development of the medical device industry. For innovative products, the NMPA will adopt an approach of "early intervention, tailored strategies for each enterprise, full-process guidance, and integrated research and review" to accelerate their market entry, better protect and promote public health, and propel China's transformation from a big pharmaceutical manufacturing country to a powerful one.

(September 29, 2024)

碳离子治疗系统获批上市

近日，国家药品监督管理局批准了兰州泰基离子技术有限公司生产的“碳离子治疗系统”产品注册。

本次批准的产品将在武汉大学人民医院经开医院投入临床应用，与已批准产品相比，治疗室均为调制扫描模式,治疗效率及治疗精度进一步提高，部分治疗室配置滑轨CT图像引导系统，图像质量、定位精度进一步提升，更好满足恶性实体肿瘤患者治疗需要。

近年来，国家药品监督管理局持续深化审评审批改革，支持医疗器械产业创新发展，满足人民群众使用高端医疗器械需求。此前，国家药品监督管理局批准的国产“碳离子治疗系统”已经用于超过1500余名患者，成效良好。

下一步，国家药品监督管理局将继续细化落实党中央改革部署的具体措施，持续支持医疗器械产业高质量发展，对创新产品按照“提前介入、一企一策、全程指导、研审联动”方式，加快上市步伐，更好保护和促进公众健康，推动我国从制药大国向制药强国迈进。

（2024-09-29）

Knee Prosthesis System Approved for Marketing

Recently, the innovative product “Knee Prosthesis System” of Abonisi Medical Technology (Suzhou) Co., Ltd. is approved by China NMPA.

This product consists of femoral components, tibial components, and patellar components, and is intended for primary knee replacement in patients with mature skeletal development. The femoral condyles and tibial trays feature a trabecular porous structure made using additive manufacturing technology at the bone integration interface, which provides a high coefficient of friction and excellent bone integration properties.

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

(November 1, 2024)

膝关节假体系统获批上市

近日，国家药品监督管理局批准了雅博尼西医疗科技（苏州）有限公司“膝关节假体系统”创新产品注册申请。

该产品由股骨部件、胫骨部件和髌骨部件组成，适用于骨骼发育成熟患者的初次膝关节置换术。其中，股骨髁及胫骨托与骨结合界面均复合有采用增材制造工艺制作的骨小梁多孔结构，具有高摩擦系数和良好的骨结合性能。

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。

（2024-11-01）

Intracranial Aneurysm Embolization Assist Stent Approved for Marketing

Recently, the innovative product “Intracranial Aneurysm Embolization Assist Stent” of Shanghai HeartCare Medical Technology Co., Ltd. is approved by China NMPA.

The product consists of three parts: the stent, delivery wire, and introducer sheath. The stent is laser-etched from nitinol tubing and features platinum-iridium markers at both ends and in the middle of some models, facilitating precise clinical assessment of stent deployment and wall apposition. Under standard clinical interventional surgical conditions, the stent is used in conjunction with angiography to determine the location of intracranial aneurysms, aiding in the endovascular embolization and blood flow reconstruction for patients with intracranial aneurysms.

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

(November 1, 2024)

颅内动脉瘤栓塞辅助支架获批上市

近日，国家药品监督管理局批准了上海心玮医疗科技股份有限公司“颅内动脉瘤栓塞辅助支架”创新产品注册申请。

该产品由支架、输送导丝和导入鞘三部分组成，其中支架部分由镍钛合金管材经激光雕刻而成，在支架两端及部分型号中部有铂铱显影点，便于临床精准判断支架打开及贴壁情况。在临床标准介入手术操作条件下，根据血管造影术来确定颅内动脉瘤位置，用于颅内动脉瘤患者血管内辅助栓塞和重建血流。

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

（2024-11-01）

Innovative Neurosurgical Planning Software Approved for Marketing

Recently, the innovative product "Neurosurgical Planning Software" of Sinovation (Beijing) Medical Technology Co., Ltd. is approved by China NMPA. This marks the 300th innovative medical device to receive approval.

This product consists of software installation programs and authorization files. The software function module includes: user login, patient sequence management, surgical planning, image registration, 3D reconstruction, stereotactic frame parameter calculation, and fiber tract generation. It is designed to develop neurosurgical planning.

This product employs multi-dimensional spatial vascular reconstruction and avoidance technology, which enables the optimization of surgical paths and improves clinical efficiency by combining existing head frame tools and planning paths. This technology is at the forefront of international standards and is pioneering in its field.

Innovative medical devices represent a new quality productive force in the medical device sector. In recent years, the NMPA has deepened reforms in the review and approval system for medical devices, addressing "blockages" and "difficulties" in the development of the medical device industry. The NMPA has continuously improved mechanisms to support the development of innovative medical devices, particularly focusing on areas such as medical robotics, artificial intelligence, medical imaging, and biomaterials, targeted research support initiatives, while strengthening inter-departmental cooperation to accelerate the listing and application of innovative products to better meet the public's demand for medical devices.

Moving forward, the NMPA will thoroughly implement the spirit of the Third Plenary Session of the 20th Central Committee of the Communist Party of China, focusing on the primary task of promoting high-quality development. The NMPA will implement the reform measures proposed in the Resolution of CPC Central Committee on Further Deepening Reform Comprehensively to Advance Chinese Modernization, advance the legislation of medical device management laws, and continue to provide enhanced support and guidance for the research and development of innovative medical devices. More resources will be allocated to the review and approval processes, ensuring that the benefits of medical device sector reforms are more equitably shared among the people.

(November 7, 2024)

脑外科手术计划软件创新产品获批上市

近日，国家药品监督管理局批准了华科精准（北京）医疗科技有限公司的脑外科手术计划软件创新产品注册申请，这是第300个获批的创新医疗器械。

该产品由软件安装程序和授权文件组成，功能模块包括:用户登录、患者序列管理、手术计划、图像配准、三维重建、头架参数计算、纤维束生成，用于制定脑外科手术计划。

该产品采用多维度空间血管重建和规避技术，通过结合现有头架工具和规划路径，可实现手术路径的优化，提高临床工作效率。该技术达到国际先进水平，具有首创性。

创新医疗器械是医疗器械领域新质生产力的代表，近年来，国家药监局深化医疗器械审评审批制度改革，深入研究医疗器械产业发展"堵点""难点"，不断健全支持创新医疗器械发展机制，特别是以问题为导向，聚焦医用机器人、人工智能、医学影像和生物材料医疗器械等重点领域，研究针对性支持举措，同时强化部门协作，加速创新产品上市和应用,更好满足公众用械需求。

下一步，国家药监局将深入贯彻党的二十届三中全会精神，聚焦推动高质量发展这一首要任务，落实《中共中央关于进一步全面深化改革、推进中国式现代化的决定》提出的改革举措，推进医疗器械管理法立法，持续加大对创新医疗器械研发申报的支持指导，倾斜更多审评审批资源，让医疗器械领域改革发展成果更多更公平惠及人民群众。

（2024-11-07）

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-copy of the Newsletter, please visit http://www.ccfdie.org

备 注：
- Newsletter中所有中文信息均摘自报刊及网络。英文均系中文翻译。如有出入，请以中文为准。
- 电子版Newsletter阅览请登录网站http://www.ccfdie.org

China Center for Food and Drug International Exchange (CCFDIE)
中国食品药品国际交流中心
Address: Room 1106, 11th Floor, Office Building B, Maples International Center, No.32, Xizhimen North Street, Haidian District, Beijing, 100082, PR.C. ,
中国北京市海淀区西直门北大街32号枫蓝国际中心B座写字楼11层1106室
邮编:100082
Tel: 010-8221 2866
Email: ccfdie@ccfdie.org
Fax: 010-8221 2857
Website: www.ccfdie.org