NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

Headline

Rules for Labels of Prepared Slices of Chinese Crude Drugs Issued by China NMPA

To further standardize the regulation on labels of prepared slices of Chinese crude drugs, in accordance with laws, administrative regulations and provisions including the *Drug Administration Law of the People's Republic of China*, the *Regulations for Implementation of the Drug Administration Law of the People's Republic of China* and the *Provisions for Drug Insert Sheets and Labels*, the NMPA organized to formulate the *Rules for Labels of Prepared Slices of Chinese Crude Drugs*, which is hereby released and shall be implemented since August 1, 2024. The labeling of expiration date according to the Rules shall be implemented since August 1, 2025.

Annex : *The Rules for Labels of Prepared Slices of Chinese Crude Drugs*

The NMPA

July 12, 2023

(July 14, 2023)

头条

国家药监局关于发布《中药饮片标签管理规定》的公告（2023年第90号）

为进一步规范中药饮片标签的管理，根据《中华人民共和国药品管理法》《中华人民共和国药品管理法实施条例》《药品说明书和标签管理规定》等法律、行政法规和规章，国家药监局组织制定了《中药饮片标签管理规定》，现予发布，自2024年8月1日起施行，其中，保质期的标注自2025年8月1日起施行。

特此公告。

附件：中药饮片标签管理规定

国家药监局

2023年7月12日

（2023-07-14）

Drugs

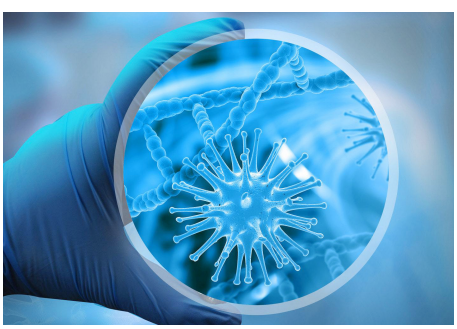
Equecabtagene Autoleucel Injection Approved with Conditions by China NMPA

Recently, the Equecabtagene Autoleucel injection(Chinese trade name: 福可苏) of Nanjing IASO Biotechnology is approved with conditions through the priority review and approval procedure by China NMPA. It is indicated for the treatment of adults with relapsed or refractory multiple myeloma (RRMM) after three or more prior lines of therapy and progressed, including a proteasome inhibitor and an immunomodulatory agent.

Equecabtagene Autoleucel Injection is an autologous cellular immunotherapy that involves integrating the chimeric antigen receptor (CAR) gene targeting B-cell maturation antigen (BCMA) into the patient's own peripheral blood CD3-positive T cells using a lentiviral vector. Once reinfused into the patient's body, these modified T cells recognize the BCMA target on the surface of multiple myeloma cells and kill them.

The approval of this product provides a novel treatment option for patients with relapsed or refractory multiple myeloma.

(June 30, 2023)



药品

国家药监局附条件批准伊基奥仑赛注射液上市

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南京驯鹿生物医药有限公司申报的伊基奥仑赛注射液（商品名：福可苏）上市。该药品用于治疗复发或难治性多发性骨髓瘤成人患者，既往经过至少3线治疗后进展（至少使用过一种蛋白酶体抑制剂及免疫调节剂）。

伊基奥仑赛注射液是一种自体免疫细胞注射剂，系采用慢病毒载体将靶向B细胞成熟抗原（BCMA）的嵌合抗原受体（CAR）基因整合入患者自体外周血CD3阳性T细胞后制备。回输患者体内后，通过识别多发性骨髓瘤细胞表面的BCMA靶点杀伤肿瘤细胞。

该品种的上市为复发或难治性多发性骨髓瘤成人患者提供了新的治疗选择。

（2023-06-30）

Published by
China Center for Food and Drug International Exchange

Telpegfilgrastim Injection Approved for Marketing by China NMPA

Recently, the Telpegfilgrastim injection (Chinese trade name: 珮金) of Xiamen Amoytop Biotech Co., Ltd. is approved for marketing by China NMPA. This drug is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

The Telpegfilgrastim injection is a Y-shaped polyethylene glycol (PEG) modified human granulocyte colony-stimulating factor (rhG-CSF), which stimulates bone marrow hematopoietic stem cells to differentiate into granulocytes, promotes the proliferation, maturation, and release of granulocytes, and restores the number of granulocytes in peripheral blood, to decrease the incidence of infection in tumor patients after chemotherapy. The marketing of this drug provides more treatment options for patients.

(June 30, 2023)

Pegmolesatide Injection Approved for Marketing by China NMPA

Recently, the Category 1 innovative drug Pegmolesatide Injection (Chinese trade name: 圣罗莱) of Jiangsu Hansoh Pharmaceutical Group Company Limited is approved by China NMPA. The drug is indicated to treat anemia in chronic kidney disease (CKD) adult patients who have not received erythropoiesis-stimulating agents (ESA) and not on dialysis; as well as who are receiving short-acting erythropoietintreatment and on dialysis (this drug is not for use as a substitute for red blood cell transfusions in patients who need immediate treatment for anemia).

Pegmolesatide is a long-acting peptide-based ESA, which promotes the proliferation of red blood cells in the body and improves anemia and related symptoms in patients with CKD. The approval of this drug provides a new treatment option for CKD patients with anemia.

(June 30, 2023)

Vorolanib Tablets Approved for Marketing by China NMPA

Recently, the Category 1 innovative drug Vorolanib Tablets (Chinese trade name: 伏美纳) of Betta Pharmaceuticals Co., Ltd is approved by China NMPA. It is used in combination with everolimus, indicated for the treatment of patients with advanced renal cell carcinoma who have previously receive tyrosine kinase inhibitor treatment but failed.

Voronib is a multi-kinase inhibitor, which has strong inhibitory effects on VEGFR2, KIT, PDGFR, FLT3 and RET, and exerts anti-tumor effect mainly by inhibiting the formation of new blood vessels. The marketing of this drug provides new treatment options for patients with advanced renal cell carcinoma.

(June 8, 2023)

国家药监局批准拓培非格司亭注射液上市

近日，国家药品监督管理局批准厦门特宝生物工程股份有限公司申报的拓培非格司亭注射液（商品名：珮金）上市。该药品适用于非髓性恶性肿瘤患者在接受容易引起发热性中性粒细胞减少症的骨髓抑制性抗癌药物治疗时，降低以发热性中生粒细胞减少症为表现的感染发生率。

拓培非格司亭注射液为Y型聚乙二醇（PEG）修饰的人粒细胞刺激因子（rhG-CSF），通过刺激骨髓造血干细胞向粒细胞分化，促进粒细胞增殖、成熟和释放，恢复外周血中性粒细胞数量，以降低肿瘤患者化疗后的感染发生率。该品种的上市为患者提供了更多的治疗选择。

（2023-06-30）

国家药监局批准培莫沙肽注射液上市

近日，国家药品监督管理局批准江苏豪森药业集团有限公司申报的1类创新药培莫沙肽注射液（商品名：圣罗莱）上市。该药适用于未接受红细胞生成刺激剂（ESA）治疗的成人非透析患者，及正在接受短效促红细胞生成素（EPO）治疗的成人透析患者（本品不适用于在需要立即纠正贫血的患者中替代红细胞输注）。

培莫沙肽是长效多肽类EPO受体激动剂，可促进体内红细胞增殖，改善慢性肾病患者的贫血及相关症状。该药品的上市为慢性肾病引起的贫血患者提供了新的治疗选择。

（2023-06-30）

国家药监局批准伏罗尼布片上市

近日，国家药品监督管理局批准贝达药业股份有限公司申报的1类创新药伏罗尼布片（商品名：伏美纳）上市。该药品与依维莫司联合，用于既往接受过酪氨酸激酶抑制剂治疗失败的晚期肾细胞癌患者。

伏罗尼布为多靶点受体酪氨酸激酶抑制剂，对VEGFR2、KIT、PDGFR、FLT3和RET均有较强的抑制作用，主要通过抑制新生血管形成发挥抗肿瘤作用。该药品的上市为晚期肾细胞癌患者提供了新的治疗选择。

（2023-06-08）

Iruplinalkib Tablets Approved for Marketing by China NMPA

Recently, the Category 1 innovative drug Iruplinalkib Tablets (Chinese trade name: 启欣可) of Qilu Pharmaceuticals Co., Ltd is approved by China NMPA. It is indicated for the treatment of anaplastic lymphoma kinase (ALK) positive and locally advanced or metastatic non-small cell lung cancer (NSCLC) patients who have been treated with crizotinib and experienced disease progression or who are crizotinib -resistant.

Iruplinalkib is an ALK inhibitor that can inhibit the phosphorylation of ALK and c-ros oncogene 1 (ROS1) kinase, thereby blocking the activation of downstream signaling pathway proteins such as ERK, STAT5, and AKT, and further inducing tumor cell death (apoptosis). The marketing of this drug provides new treatment options for ALK positive locally advanced or metastatic NSCLC patients.

(June 28, 2023)

国家药监局批准伊鲁阿克片上市

近日，国家药品监督管理局批准齐鲁制药有限公司申报的1类创新药伊鲁阿克片（商品名：启欣可）上市。该药适用于既往接受过克唑替尼治疗后疾病进展或对克唑替尼不耐受的间变性淋巴瘤激酶（ALK）阳性的局部晚期或转移性非小细胞肺癌（NSCLC）患者的治疗。

伊鲁阿克为ALK抑制剂，可通过抑制ALK和ROS1激酶的磷酸化进而阻断ERK、STAT5和AKT等下游信号通路蛋白的激活，从而诱导肿瘤细胞死亡（凋亡）。该药品的上市为ALK阳性的局部晚期或转移性非小细胞肺癌（NSCLC）患者提供了新的治疗选择。

（2023-06-28）

Innovative TCM Shenyu Ningshen Tablet Approved for Marketing by China NMPA

Recently, the Category 1.1 innovative traditional Chinese medicine (TCM) Shenyu Ningshen Tablets of Guangdong Siji Pharmaceutical Co., Ltd was approved for marketing by China NMPA.

A randomized, double-blind, placebo-controlled multicenter clinical trial was conducted on this medicine, and the results showed that in regard of the primary efficacy endpoints (HAMD-17 score reduction rate ≥ 50% is recognized as effective) compared between groups, the efficacy of the treatment group was better than that of the placebo group.

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

(June 8, 2023)

国家药监局批准中药创新药参郁宁神片上市

近日，国家药品监督管理局批准了广东思济药业有限公司申报的中药1.1类创新药参郁宁神片上市。

该药品开展了随机、双盲、安慰剂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评分减分率≥50%为有效）有效率组间比较，试验组疗效优于安慰剂组。

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

（2023-06-08）

Oteseconazole Capsules Approved for Marketing by China NMPA

Recently, the Category 1 innovative drug Oteseconazole Capsules of eVENUS PHARMACEUTICAL LABORATORIES INC. is approved by China NMPA. It is indicated for the treatment of severe vulvovaginal candidiasis (VVC).

Oteseconazole, as an antifungal drug, is an azole metalloenzyme inhibitor that targets fungal sterol 14α demethylase (CYP51). The marketing of this drug provides new treatment options for patients with severe VVC.

(June 28, 2023)

国家药监局批准奥特康唑胶囊上市

近日，国家药品监督管理局批准eVENUS PHARMACEUTICAL LABORATORIES INC.申报的1类创新药奥特康唑胶囊上市。该药品用于治疗重度外阴阴道假丝酵母菌病（VVC）。

奥特康唑是一种抗真菌药物，属唑类金属酶抑制剂，靶向抑制真菌甾醇14α去甲基化酶（CYP51）。该药品的上市为重度外阴阴道假丝酵母菌病（VVC）患者提供了新的治疗选择。

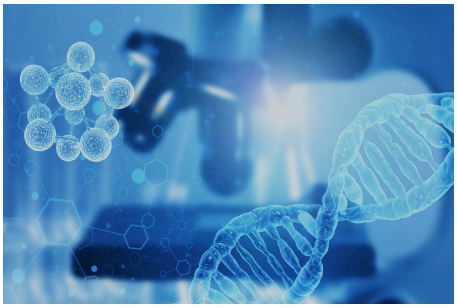
（2023-06-28）

Retagliptin Phosphate Tablets Approved for Marketing by NMPA

Recently, the Category 1 innovative drug Retagliptin Phosphate Tablets (Chinese trade name: 瑞泽唐) of Jiangsu Hengrui Pharmaceuticals Co., Ltd. is approved by China NMPA. It is indicated for improving the blood glucose control for adult patients with type 2 diabetes.

Retagliptin Phosphate is a dipeptidyl peptidase 4(DPP-4) inhibitor that inhibits DPP-4 to hydrolyze the incretin hormone, thereby increasing the plasma concentration of active glucagon-like peptide-1 (GLP-1) and glucose dependent insulin-like polypeptide (GIP). It increases the release of insulin in a glucose dependent manner and decreases glucagon to reduce blood glucose. The marketing of this drug provides new treatment options for adult patients with type 2 diabetes.

(June 28, 2023)



国家药监局批准磷酸瑞格列汀片上市

近日，国家药品监督管理局批准江苏恒瑞医药股份有限公司申报的1类创新药磷酸瑞格列汀片(商品名：瑞泽唐)上市，该药适用于改善成人2型糖尿病患者的血糖控制。

磷酸瑞格列汀是二肽基肽酶4 (DPP-4)抑制剂，通过抑制DPP-4水解肠促胰岛激素，从而增加活性形式的胰高血糖素样肽-1(GLP-1)和葡萄糖依赖性促胰岛素多肽(GIP)的血浆浓度，以葡萄糖依赖的方式增加胰岛素释放并降低胰高血糖素水平，进而降低血糖。该药品的上市为成人2型糖尿病患者提供了新的治疗选择。

(2023-06-28)

NMPA Announcement on Adopting ICH Guidelines M10 Q&As and FAQs

To align the technical standards for drug registration with international standards, the NMPA upon deliberation decided to adopt the ICH(International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) Guidelines M10: Bioanalytical Method Validation And Study Sample Analysis (hereinafter referred to as M10) Q&As documents and FAQs documents. The relevant items are hereby announced as follows:

1. The relevant studies starting from July 29, 2023 (based on the original record time of biological sample analysis) are applicable to M10 Q&As documents and FAQs documents.

2. The relevant technical guidelines may be accessed on the website of the Center for Drug Evaluation of NMPA. The CDE of NMPA shall carry out technical guidance in relation to the implementation of this Announcement.

The National Medical Products Administration

June 29, 2023

(July 4, 2023)

国家药监局关于适用《M10：生物分析方法验证及样品分析》国际人用药品注册技术协调会指导原则问答文件和常见问题解答文件的公告(2023年第84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《M10：生物分析方法验证及样品分析》国际人用药品注册技术协调会指导原则 (以下简称M10) 问答文件和常见问题解答文件。现就有关事项公告如下：

一、自2023年7月29日起开始的相关研究(以生物样品分析原始记录时间点为准)，均适用M10问答文件和常见问答解答文件。

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6月29日

(2023-07-04)

Anaprazole Sodium Enteric-coated Tablets Approved for Marketing by China NMPA

Recently, the Category 1 innovative drug Anaprazole Sodium Enteric-coated Tablets (Chinese trade name: 安久卫) of Xuanzhu (Beijing) Pharmaceutical Technology Co., Ltd. is approved by China NMPA. It is an innovative drug independently developed in

国家药监局批准安奈拉唑钠肠溶片上市

近日，国家药品监督管理局批准轩竹(北京)医药科技有限公司申报的1类创新药安奈拉唑钠肠溶片(商品名：安久卫)上市。该药为

China and has independent intellectual property rights, indicated for the treatment of duodenal ulcers.

Anaprazole is a proton pump inhibitor and belongs to benzimidazole compounds. It can inhibit gastric acid secretion by inhibiting enzyme activity of the H+- K+-ATP of parietal cell and reducing the proton transport capacity. The marketing of this drug provides new treatment options for patients with duodenal ulcers.

(June 25, 2023)

我国自主研发并拥有自主知识产权的创新药，适用于治疗十二指肠溃疡。

安奈拉唑为质子泵抑制剂，属于苯并咪唑类化合物，可通过抑制胃壁细胞H+–K+–ATP酶活性和降低质子转运能力而抑制胃酸分泌。该药品的上市为十二指肠溃疡患者提供了新的治疗选择。（2023-06-25）

Medical Devices

Coronary Interventional Surgical Control System with One-off Accessories Approved for Marketing

Recently, the innovative product Coronary Interventional Surgical Control System with one-off accessories of Corindus Inc. is approved by China NMPA.

The coronary interventional surgery control system, used with its accessories, assists clinical doctors in delivering and operating guide wires, guide catheters, or quickly exchanging balloon dilation catheters/stents during percutaneous coronary interventional surgery.

Compared with traditional coronary interventional surgery methods, doctors drive the robotic arm and the supporting accessories installed at the end through the operating console of this product in a shielded environment, to control the intervention devices, which reduces the radiation exposure of doctors during surgery. Moreover, this product can achieve quantitative vascular size measurement and assist doctors in determining the length of lesions.

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

(June 1, 2023)

医疗器械

冠状动脉介入手术控制系统及其一次性使用附件获批上市

近日，国家药品监督管理局批准了Corindus Inc.生产的“冠状动脉介入手术控制系统”及“一次性使用冠状动脉介入手术控制系统附件”创新产品注册申请。

冠状动脉介入手术控制系统和一次性使用冠状动脉介入手术控制系统附件配套使用，辅助临床医生在经皮冠状动脉介入手术期间，输送和操作导丝、导引导管或者快速交换球囊扩张导管/支架。

与传统冠状动脉介入手术方式相比，医生在屏蔽环境下通过该产品的操作控制台，驱动机械臂及其末端安装的配套附件，实现对介入器械的操控，减少了医生在手术中的射线暴露，并且该产品可实现量化的血管尺寸测量，辅助医生判断病变长度。

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。

(2023-06-01)

Computer-aided Detection Software for Electronic Endoscope for Colon Polyps Approved for Marketing

Recently, the innovative product computer-aided detection software for electronic endoscope for colon polyps of Tencent Healthcare (Shenzhen) Co., Ltd. is approved by China NMPA.

This product is applied for adult colon polyp examination by displaying suspected polyp areas in the video images output by electronic endoscope devices. Its principle is to import video image signal into the video stream output by the image processor of the electronic endoscope, mark the suspected polyp position after analysis of software deep learning algorithms, and display it on the video client, without affecting the original image display of the electronic endoscope. Doctors assess the presence of polyps based on the patient's condition and the labeled images in the electronic endoscope.

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

(June 1, 2023)

结肠息肉电子内窥镜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腾讯医疗健康（深圳）有限公司生产的“结肠息肉电子内窥镜图像辅助检测软件”创新产品注册申请。

该产品用于成人结肠息肉检查，可在电子内窥镜设备输出视频图像中显示疑似息肉区域。其原理是在电子内窥镜图像处理器输出的视频流中导入视频图像信号，经过软件深度学习算法分析后将疑似息肉位置进行标记，并在视频客户端显示，电子内窥镜原始图像显示不受影响。医生结合患者病情，根据电子内窥镜标记图像，研判是否存在息肉。

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。

(2023-06-01)

Carbon Ion Therapy System Approved for Marketing

Recently, the innovative product Carbon Ion Therapy System of Lanzhou Ion Therapy Co., Ltd. is approved by China NMPA.

This product is the second domestic Carbon Ion Therapy System which is on par with international standards and with independent intellectual property rights. The approval of this products marks another important step forward of homemade high-end medical devices in China, and is of great significance for improving the methods and levels of tumors diagnosis and treatment in China.

This product includes 4 treatment terminals. Compared with the formerly approved carbon ion therapy system, it adds 2 more therapy rooms, the 45 ° and the 90 ° beam therapy room, reduces the beam spot size of the modulation scanning head, improves the beam intensity, shortens the beam turn-off time, configures an image guidance system, and upgrades the patient support device, therefore improving the efficiency and safety of treatment. After being approved, this product will further improve the treatment level, reduce treatment costs, and meet the treatment needs of patients with malignant solid tumors.

The practitioners should strictly use the product in accordance with the approved scope of application, and at the same time, strictly comply with the diagnostic and treatment standards of the health department.

Taking it as an innovative high-end product, China NMPA in accordance with the principle of "early intervention, special person in charge, whole process guidance and scientific review and approval", conducted active communication, made adjustment regularly and coordinated multiple departments to enhance the guidance of registration application and accelerate the marketing process of this product, so as to on the premise of ensuring safety and effectiveness, better meet the needs of patients to use high-end medical devices.

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

(June 3, 2023)

碳离子治疗系统获批上市

近日，国家药品监督管理局附条件批准了兰州科近泰基新技术有限责任公司生产的“碳离子治疗系统”创新产品注册申请。

该产品为我国第二款具有自主知识产权的国产碳离子治疗系统，性能指标达到国际水平。该产品的获批，标志着我国高端医疗器械国产化又迈出重要一步，对于提升我国医学肿瘤诊疗手段和水平，具有重大意义。

该产品包含4个治疗室，与此前已批准国产碳离子产品相比，增加45度和90度2个治疗室，缩小调制扫描治疗头束斑尺寸，提升束流强度，缩短束流关断时间，配置图像引导系统，升级患者支撑装置，提升了治疗的效率和安全性。该产品获批上市后，将进一步提升治疗水平，降低治疗成本，满足恶性实体肿瘤患者治疗需要。

使用者应当严格按照产品批准的适用范围使用产品，同时应当严格遵守卫生健康部门的诊疗规范。

作为创新高端医疗器械，国家药监局按照“提前介入、专人负责、全程指导、科学审批”原则，积极沟通、定期调度、多方协调，加大对该产品注册申报的指导力度，在保证产品安全、有效基础上全力加快上市进程，以更好地满足患者使用高水平医疗器械的需要。

药品监督管理部门将加强产品上市后监管，有效保护患者用械安全。

(2023-06-03)

Implantable Left Ventricular Assist System Approved for Marketing

Recently, the innovative product Implantable Left Ventricular Assist System of Shenzhen Core Medical Technology Co., Ltd is approved by China NMPA, which is the fourth domestic Implantable Left Ventricular Assist System.

This product is composed of implanted parts, external parts and surgical accessories, and is used together with specific artificial blood vessels to provide mechanical support for the blood circulation of patients with progressive refractory left heart failure, and is indicated for transitional treatment before heart transplantation or to restore heart function.

This product is the third generation non-contact magnetic levitation centrifugal pump, with the core technology of disc motor technology. It uses position sensors to detect and control the rotor speed and suspension height. The motor of this product only uses a set of stator coils to control the rotation and suspension of the rotor at the same time, which enables this product with simpler structure, lighter weight, smaller size, and lower power consumption. In clinical trials, the surgical incision is smaller and thus patients recover faster. It is applicable to a wider population, and can reduce the risk of thrombosis caused by pump heat.

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

(June 6, 2023)

植入式左心室辅助系统获批上市

近日，国家药品监督管理局批准了深圳核心医疗科技有限公司生产的“植入式左心室辅助系统”创新产品注册申请，为我国第四款植入式左心室辅助系统。

该产品由植入部件、体外部件、手术附件组成，与特定人工血管配套使用，为进展期难治性左心衰患者血液循环提供机械支持，用于心脏移植前或恢复心脏功能的过渡治疗。

该产品为第三代非接触式磁悬浮离心泵，核心技术主要为盘式电机技术，其利用位置传感器检测并控制转子的转速和悬浮高度。该产品电机仅采用一组定子线圈同时控制转子的旋转和悬浮，结构更简单、重量更轻、体积更小、功耗更低，在临床应用中，手术切口较小，患者恢复较快，适用人群更广，并可降低血泵热量导致的血栓风险。

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。 (2023-06-06)

Multimodal Tumor Treatment System Approved for Marketing

Recently, the innovative product Multimodal Tumor Treatment System of Shanghai Magic Medical Technology Co., Ltd. is approved for marketing by China NMPA.

This product is a multimodal treatment system that integrates liquid nitrogen freezing and radio frequency (RF) heating. Through pre-freezing the target lesion, followed by RF heating and precise control of the process, it achieves multimodal tumor ablation where the heating area overlaps with the freezing area, thereby realizing precise treatment of the lesion.

This product overcomes the problem of gas resistance by optimizing the design of the ablation probe, and therefore achieves efficient phase change heat transfer. In the treatment section of the ablation probe, precise measurement and real-time feedback of tumor tissue during the treatment process are achieved by shielding against RF interference. High vacuum technology is used in the non-treatment section of the ablation probe to construct an ultra-thin vacuum insulation layer to shield against RF electromagnetic field, while completely ablating the tumor and minimizing damage to the surrounding tissues. The integrated control system can also realize the visualization of ablation area by precisely controlling the pre-freezing and RF heating processes.

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

(June 9, 2023)

多模态肿瘤治疗系统获批上市

近日，国家药品监督管理局批准了上海美杰医疗科技有限公司生产的多模态肿瘤治疗系统创新产品注册申请。

该产品是集液氮冷冻与射频加热于一体的多模态治疗系统，通过对目标病灶预冷冻，后续进行射频加热并对过程精确控制，从而实现加热区域与冷冻区域重合的多模态肿瘤消融，达到病灶精准治疗效果。

该产品通过对消融针设计优化，有效克服气阻问题，实现高效相变换热。在消融针治疗段通过屏蔽射频干扰，实现治疗过程中肿瘤组织精准测量与实时反馈。在消融针非治疗段采用高真空工艺技术，构建超薄真空绝热层，实现射频电磁场屏蔽，在完全消融肿瘤的同时，最大程度避免周围组织的损伤。一体化控制系统通过对预冷冻和射频加热过程的精准控制，还可实现消融区域的可视化。

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。 (2023-06-09)

Implantable Sacral Nerve Stimulation System Approved for Marketing

Recently, three innovative products, the Implantable Sacral Nerve Stimulator, Implantable Sacral Nerve Stimulation Extension Wire and Implantable Sacral Nerve Stimulation Electrode of Hangzhou Chengnuo Medical Technology Ltd. are approved by China NMPA.

These three products are used together to form the implantable sacral nerve stimulation system, of which the core technology has independent intellectual property rights. The system can generate multiple stimulation pulse signals through the six sacral nerve stimulation contacts, and can realize the parameter regulation of stimulator in non-close contact by using the far field programmable communication technology. Moreover, the system, combined with six contact electrodes, can provide more combinations of stimulus, refine the regulatory range, and add treatment methods for lower urinary tract dysfunction, so as to further meet the clinical needs of patients.

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

(June 14, 2023)

植入式骶神经刺激系统获批上市

近日，国家药品监督管理局批准了杭州承诺医疗科技有限公司生产的“植入式骶神经刺激器”、“植入式骶神经刺激延伸导线”、“植入式骶神经刺激电极”三个创新产品注册申请。

三个产品配套使用，构成植入式骶神经刺激系统，其核心技术具有自主知识产权。该系统通过六触点骶神经刺激输出，可产生多路刺激脉冲信号，利用远场程控通信技术可实现非近距离接触下刺激器参数调控。而且，该系统结合六触点电极可提供更多刺激组合，调控范围更加精细，并增加了下尿路功能障碍治疗方法，进一步满足患者临床需要。

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。

(2023-06-14)

Puncture Surgical Navigation Positioning System Approved for Marketing

Recently, the innovative product Puncture Surgical Navigation Positioning System of True Health (Beijing) Medical Technology Co., Ltd. is approved by China NMPA.

This product integrates navigation alignment, robotic arm positioning, and respiratory tracking into a thoraco-abdominal puncture navigation positioning system, which is the first in China. Compared with conventional CT guidance methods, this product can improve the one-time success rate for adult pulmonary and abdominal solid organ

穿刺手术导航定位系统获批上市

近日，国家药品监督管理局批准了真健康(北京)医疗科技有限公司生产的穿刺手术导航定位系统创新产品注册申请。

该产品将导航配准、机械臂定位、呼吸追踪集成为胸腹部穿刺导航定位系统，为国内

puncture surgery and reduce the number of needle insertions and CT scans, and therefore has significant value for clinical application.

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

(June 15, 2023)

首创。与常规CT引导方式相比，该产品可以提高成人肺及腹部实体器官穿刺手术的一次到位率，减少进针次数和CT扫描次数，具有显著临床应用价值。

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。

（2023-06-15）

Knee Replacement Surgical Navigation Positioning System Approved for Marketing

Recently, the innovative product Knee Replacement Surgical Navigation Positioning System of Beijing Tinavi Medical Technologies Co., Ltd. is approved by China NMPA.

This product is composed of a host, a main control trolley, and a navigation positioning tool kit. It is the first application in China to use a six-degree-of-freedom robotic arm to assist doctors in the installation of knee prosthesis during the total knee replacement surgery for adult patients. Compared with conventional methods of total knee replacement, this product can ensure the accuracy of surgical positioning, decrease the incidence of adverse events and complications, and reduce the radiation damage of X-ray to doctors and patients.

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

(July 13, 2023)

膝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批准了北京天智航医疗科技股份有限公司生产的膝关节置换手术导航定位系统创新产品注册申请。

该产品由主机、主控台车、导航定位工具包组成，在成人全膝关节置换手术过程中，应用六自由度机械臂辅助医生完成膝关节假体安装等工作，为国内首创。该产品与传统人工全膝关节置换术相比，可以保证手术定位精度，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。

（2023-07-13）

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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