2024 Volume 5

NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

Headline

Management Requirements for Temporary Import and Use of Medical Devices in Urgent Clinical Need in Medical Institutions Issued and Implemented

In order to fully implement the Regulations for the Supervision and Administration of Medical Devices (State Council Decree No. 739), and to further meet the demand for specific medical devices in urgent clinical need, the National Medical Products Administration (NMPA), in collaboration with the National Health Commission, has issued the Management Requirements for Temporary Import and Use of Medical Devices in Urgent Clinical Need in Medical Institutions (Announcement No. 97 of 2024, hereinafter referred to as the Management Requirements). This initiative aims to effectively enhance the accessibility of medical devices in urgent clinical need under special circumstances, thereby genuinely improving the health and well-being of the public.

The Management Requirements adhere to a people-centered approach, prioritizing the protection of public health. It fully takes into account the urgent need for medical devices in special situations, defining the scope of products and medical institutions. It clarifies the requirements for determining the responsibilities of medical institutions, distributors, and overseas manufacturers and agents. It also specifies the application materials, procedures, review methods, and timelines. Additionally, it outlines requirements for record-keeping, cessation of use, analysis reports, and continued use of the relevant medical devices by medical institutions.

The Management Requirements apply to the temporary import and use by medical institutions of Class II and Class III medical devices that are available in the overseas market but have no predicate device available in China due to the urgent clinical needs of patients. These devices do not include those that should be subject to large medical equipment configuration licensing management. The term "urgent clinical need" refers to the need for methods to prevent or treat serious life-threatening diseases for which there are no effective treatment or prevention methods in China.

Given that the relevant medical devices have not been approved for marketing in China, the Management Requirements stipulate that the medical institutions using these devices must be a leading high-level medical institutions with extensive experience in the diagnosis and treatment of complex and critical conditions in the relevant therapeutic areas for many years, have the ability to treat such conditions, have appropriate specialized departments and have many years of experience in the use of similar medical devices; the relevant departments should be at the forefront of clinical application of this type of device; and the medical teams using the devices should include senior experts in the field to ensure the quality of product use and patient safety.

The NMPA, in conjunction with the National Health Commission, will continue to implement these requirements, strengthen training and guidance, and actively address a small number of specific medical needs of patients.

(July 19, 2024)

头条

医疗机构临床急需医疗器械临时进口使用管理要求发布实施

为全面落实《医疗器械监督管理条例》（国务院令第739号）要求，进一步满足特定临床急需用械需求，国家药监局会同国家卫生健康委印发《医疗机构临床急需医疗器械临时进口使用管理要求》（2024年第97号公告，以下简称《管理要求》），有效提高特殊情况下临床急需医疗器械可及性，切实增进人民群众健康福祉。

《管理要求》坚持以人为本，把保障人民健康放到优先位置，充分考虑特殊情况下患者的用械需求，确定了产品范围和医疗机构范围；明确了医疗机构、经营企业和境外制造商、代理人各方责任认定要求；规定了申请材料、申请程序、审查方式和时限；提出了医疗机构使用相应医疗器械记录保存、停止使用、分析报告、继续使用等要求。

《管理要求》适用于医疗机构因患者临床急需而临时进口使用，国外已上市但国内尚无同品种产品上市的第二类、第三类医疗器械，不包括应纳入大型医用设备配置许可管理的设备。其中，临床急需是指在国内尚无有效治疗或者预防手段的情况下，临床上用于防治严重危及生命疾病所需。

考虑相应医疗器械未在我国上市，《管理要求》规定使用相应医疗器械的医疗机构必须是处于引领地位的高水平医疗机构，在相应治疗领域已开展多年疑难危重病种的诊疗服务，具有相应疑难危重症的治疗能力、相适应的专业科室、多年使用同类医疗器械经验，且相应科室应当在该类产品临床应用领域具有国内领先水平，使用相应医疗器械的医疗团队应当包括相应领域的资深专家，从而确保产品使用质量和患者用械安全。

国家药监局会同国家卫生健康委将继续做好实施工作，强化培训指导，积极解决患者少量特定医疗需求问题。

（2024-07-19）

Published by
China Center for Food and Drug International Exchange

Drugs

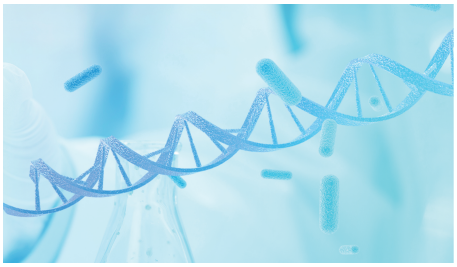
Ciltacabtagene Autoleucel Injection Approved for Marketing by China NMPA

Recently, the Ciltacabtagene Autoleucel Injection (trade name: 卡卫获/Carvykti), of Nanjing Legend Biotech Co., Ltd. is approved for marketing with conditions by China NMPA. It is indicated for the treatment of adults with relapsed or refractory multiple myeloma after three or more prior lines of therapy and progressed, including a proteasome inhibitor and an immunomodulatory agent.

The Ciltacabtagene 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 T cells using a lentiviral vector, and recognizes the BCMA target on the surface of multiple myeloma cells and kills them, thus providing a treatment for multiple myeloma.

The marketing of this product provides a new treatment option for adult patients with multiple myeloma.

(September 12, 2024)



Vunakizumab Injection Approved for Marketing by China NMPA

Recently, the Vunakizumab Injection (trade name: 安达静) of Suzhou Suncadia Biopharmaceuticals Co., Ltd. is approved by China NMPA. It is indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis through systematic treatment or phototherapy.

The Vunakizumab Injection is a recombinant humanised IgG1 subtype anti-interleukin-17A (IL-17A) monoclonal antibody that inhibits the onset and progression of inflammation by specifically binding to IL-17A protein in serum and blocking the binding of IL-17A to IL-17RA (IL-17A receptor).

The marketing of this product provides a new treatment option for adult patients with plaque psoriasis.

(September 12, 2024)

Xeligekimab Injection Approved for Marketing by China NMPA

Recently, the Xeligekimab Injection (trade name: 金立希/Jin Li Xi) of Chongqing Genrix Biopharmaceutical Co., Ltd. is approved by China NMPA. It is indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis through systematic treatment or phototherapy.

The Xeligekimab Injection is a recombinant fully human IgG4 subtype anti-interleukin-17A (IL-17A) monoclonal antibody that inhibits the onset and progression of inflammation by specifically binding to IL-17A protein in serum and blocking the binding of IL-17A to IL-17RA (IL-17A receptor).

The marketing of this product provides a new treatment option for adult patients with plaque psoriasis.

(September 12, 2024)

药品

国家药监局批准西达基奥仑赛注射液上市

近期，国家药品监督管理局附条件批准南京传奇生物科技有限公司申报的西达基奥仑赛注射液（商品名：卡卫获）上市，用于治疗既往接受过至少三线治疗后进展（至少使用过一种蛋白酶体抑制剂及免疫调节剂）的复发或难治性多发性骨髓瘤成人患者。

西达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T细胞后制备，通过识别多发性骨髓瘤细胞表面的BCMA靶点杀伤肿瘤细胞，起到治疗多发性骨髓瘤的作用。

该品种的上市为多发性骨髓瘤成人患者提供了新的治疗选择。

（2024-09-12）

国家药监局批准夫那奇珠单抗注射液上市

近期，国家药品监督管理局批准苏州盛迪亚生物医药有限公司申报的夫那奇珠单抗注射液（商品名：安达静）上市，用于治疗适合系统治疗或光疗的中度至重度斑块状银屑病成人患者。

夫那奇珠单抗注射液是一种重组人源化IgG1亚型抗白介素-17A（IL-17A）单克隆抗体，可通过特异性结合血清中的IL-17A蛋白，阻断IL-17A与IL-17RA（IL-17A受体）的结合，抑制炎症的发生和发展。

该品种的上市为斑块状银屑病成人患者提供了新的治疗选择。

（2024-09-12）

国家药监局批准赛立奇单抗注射液上市

近期，国家药品监督管理局批准重庆智翔金泰生物制药股份有限公司申报的赛立奇单抗注射液（商品名：金立希）上市，用于治疗适合系统治疗或光疗的中度至重度斑块状银屑病成人患者。

赛立奇单抗注射液是重组全人源IgG4亚型抗白介素-17A（IL-17A）单克隆抗体，可通过特异性结合血清中的IL-17A蛋白，阻断IL-17A与IL-17RA（IL-17A受体）的结合，抑制炎症的发生和发展。

该品种的上市为斑块状银屑病成人患者提供了新的治疗选择。

（2024-09-12）

Stapokibart Injection Approved for Marketing by China NMPA

Recently, the Stapokibart Injection (trade name: 康悦达) of Chengdu Kangnuoxing Biopharma, Inc. is approved by China NMPA. It is indicated for the treatment of adult patients with moderate-to-severe atopic dermatitis in adults who are inadequately controlled by topical medications or for whom topical medications are not indicated.

The Stapokibart Injection is a monoclonal antibody drug targeting IL-4Rα, which treats atopic dermatitis induced by excessive inflammatory response by blocking the binding of IL-4 and IL-13 to IL-4Rα receptor and inhibiting the release of downstream inflammatory factors, protein expression and inflammatory cell activity caused by IL-4 and IL-13.

The marketing of this product provides a new treatment option for adult patients with moderate-to-severe atopic dermatitis.

(September 12, 2024)

国家药监局批准司普奇拜单抗注射液上市

近日，国家药品监督管理局批准成都康诺行生物医药科技有限公司申报的司普奇拜单抗注射液（商品名：康悦达）上市，用于治疗外用药控制不佳或不适合外用药治疗的成人中重度特应性皮炎。

司普奇拜单抗注射液是以IL-4Rα为靶点的单克隆抗体药物，通过阻断IL-4和IL-13与IL-4Rα受体的结合，抑制IL-4和IL-13引起的下游炎症因子的释放、蛋白表达及炎症细胞活性，治疗炎症反应过度诱发的特应性皮炎。

该品种的上市为中重度特应性皮炎成人患者提供了新的治疗选择。

（2024-09-12）

Medical device

NMPA Notice on Printing and Issuing the Guidelines for On-Site Inspection of the Good Supply Practice for Medical Devices NMPA Department of Drug Supervision [2024] No. 20

To medical products administrations of all provinces, autonomous regions and municipalities directly under the central government, and Xinjiang Production and Construction Corps:

The revised Good Supply Practice for Medical Devices (hereinafter referred to as the Regulations) will be implemented as of July 1, 2024. To standardize and instruct the on-site inspection of the Good Supply Practice for Medical Devices, the National Medical Products Administration (NMPA) has formulated the Guidelines for On-site Inspection of Good Supply Practice for Medical Devices (hereafter referred to as the Guidelines), which is hereby printed and issued.

The Guidelines are applicable to the drug regulatory department based on the Regulations to conduct on-site inspection of distribution license (including change and renewal) of medical device distributors, and on-site inspection after distributing filing of medical device distributors, as well as additional various supervision and inspection of medical device distributors. During the inspection process, medical device distributors can determine the reasonable lacking items according to their distribution mode, distribution scope, distribution varieties, etc., and give the reasons in writing, which shall be confirmed by the inspection team of the drug regulatory department.

I. On-site inspection of medical device distribution license (including change and renewal)

During the process of on-site inspection of medical device distribution license (including change and renewal), for the distributor applicable items that all meet the requirements or can be rectified on-site, the inspection result shall be "passed"; if the number of non-compliant items in the key items (marked as "※" items) is ≤ 10% and the number of non-compliant items in the general items (unmarked items) is ≤ 20%, the inspection result shall be "rectified within a specified time"; If the number of non-compliant items in key items is > 10% or the number of non-compliant items in general items is > 20%, the inspection result shall be "failed".

If the inspection result is "rectified within a specified time", the distributor should complete the rectification within 30 working days after the end of the on-site inspection and submit a

医疗器械

国家药监局关于印发医疗器械经营质量管理规范现场检查指导原则的通知

各省、自治区、直辖市和新疆生产建设兵团药品监督管理局：

新修订的《医疗器械经营质量管理规范》（以下简称《规范》）自2024年7月1日起施行。为规范和指导医疗器械经营质量管理规范现场检查工作，国家药监局组织制定了《医疗器械经营质量管理规范现场检查指导原则》（以下简称《指导原则》），现予印发。

本《指导原则》适用于药品监督管理部门依据《规范》，对医疗器械经营企业经营许可（含变更和延续）现场核查，或者经营备案后的现场检查，以及其他各类监督检查。检查过程中，医疗器械经营企业可以根据其经营方式、经营范围、经营品种等特点，确定合理缺项项目，并书面说明理由，由药品监督管理部门的检查组予以确认。

一、医疗器械经营许可（含变更和延续）现场核查

对医疗器械经营企业经营许可（含变更和延续）现场核查中，企业适用项目全部符合要求或者能够当场整改完成的，检查结果为"通过检查"；关键项目（标识为"※"项）中不符合要求的项目数≤10%且一般项目（无标识项）中不符合要求的项目数≤20%的，检查结果为"限期整改"；关键项目中不符合要求的项目数>10%或者一般项目中不符合要求的项目数>20%的，检查结果为"未通过检查"。

one-off rectification report to the original inspection department. If the review concludes that all rectification items meet the requirements, the drug regulatory department will issue a written decision to grant a license. If the distributor fails to submit a rectification report within 30 working days or the review concludes that there are still items that do not meet the requirements, the drug regulatory department will issue a written decision not to grant a license. If the inspection result is "failed", the drug regulatory department can directly issue a written decision not to grant a license.

In this Guidelines, the percentage of non-conforming critical items = Number of non-conforming critical items ÷ (Total number of critical items - Number of confirmed reasonable lacking critical items) × 100%; The percentage of non-conforming general items = Number of non-conforming general items ÷ (Total number of general items - Number of confirmed reasonable lacking general items) × 100%.

II. Additional supervision and inspection

During the process of daily supervision and inspection and on-site inspection after distributing filing of medical device distributor, for the distributor applicable items that all meet the requirements or can be rectified on-site, the inspection result shall be "passed". If any item does not meet the requirements and cannot be rectified on-site, the inspection result shall be "rectified within a specified time".

If, during the inspection, the distributor is found to have violated the relevant provisions of the Regulations for the Supervision and Administration of Medical Devices as well as Provisions for Supervision and Administration of Medical Device Distribution, it shall be dealt with in accordance with laws and regulations. Among them, if the non-conformity items found in the inspection affect or fail to ensure the safety and efficacy of the products, after evaluation by the drug regulatory department, they shall be dealt with in accordance with the provisions of Article 86 of the Regulations for the Supervision and Administration of Medical Devices, and Articles 22 and 24 of the Provisions for Supervision and Administration of Medical Device Distribution, in accordance with the laws.

This Guidelines shall be implemented as of the date of issuance. The Guidelines for On-Site Inspection of the Good Supply Practice for Medical Devices (CFDA Department of Medical Device Supervision [2015] No. 239) issued by the former China Food and Drug Administration is annulled simultaneously.

National Medical Products Administration

July 30, 2024

(July 30, 2024)

检查结果为"限期整改"的，企业应当在现场检查结束后30个工作日内完成整改并向原检查部门一次性提交整改报告。经复查后，整改项目全部符合要求的，药品监督管理部门作出准予许可的书面决定。企业在30个工作日内未能提交整改报告或者经复查仍存在不符合要求项目的，药品监督管理部门作出不予许可的书面决定。检查结果为"未通过检查"的，药品监督管理部门可以直接作出不予许可的书面决定。

本《指导原则》所指的关键项目中不符合要求的项目数比例=关键项目中不符合要求的项目数÷（关键项目数总数—关键项目中确认的合理缺项项目数）×100%；一般项目中不符合要求的项目数比例=一般项目中不符合要求的项目数÷（一般项目数总数——一般项目中确认的合理缺项项目数）×100%。

二、其他监督检查

对医疗器械经营企业日常监督检查和经营备案后的现场检查中，企业适用项目全部符合要求或者能够当场整改完成的，检查结果为"通过检查"。有项目不符合要求的且不能当场整改完成的，检查结果为"限期整改"。

检查中发现企业违反《医疗器械监督管理条例》《医疗器械经营监督管理办法》有关规定的，应当依法依规处置。其中，经药品监督管理部门组织评估，检查发现的不符合项目影响或者不能保证产品安全、有效的，依据《医疗器械监督管理条例》第八十六条、《医疗器械经营监督管理办法》第二十二条、第二十四条等规定依法处置。

本《指导原则》自发布之日起施行。原食品药品监管总局印发的《医疗器械经营质量管理规范现场检查指导原则》（食药监械监〔2015〕239号）同时废止。

国家药监局

2024年7月30日

（2024-07-30）

Grency® Iliac Vein Stent System Approved for Marketing

Recently, the innovative product "Grency® Iliac Vein Stent System" produced by Hangzhou Weiqiang Medical Technology Co., Ltd. is approved by China NMPA.

The product consists of a stent and a delivery device. The stent, which is pre-loaded within the delivery device, is a self-expanding nickel titanium alloy stent with tantalum markers for radiopacity. The delivery device consists of a sheath core, a sheath connector, a haemostatic valve, a handle and a rear handle. The product is sterilized by ethylene oxide and is intended for single use. This product is intended to be applied in the common iliac vein for the treatment of non-thrombotic iliac vein compression syndrome.

The stent features a proximal tapered and flared venous stent design, an open-loop midsection, and a segmented structure that enhances product properties to meet clinical needs.

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

(July 11, 2024)

髂静脉支架系统获批上市

近日，国家药品监督管理局经审查，批准了杭州唯强医疗科技有限公司生产的"髂静脉支架系统"创新产品注册。

该产品由支架和输送器组成，支架预装在输送器内，支架为自膨式镍钛合金支架，显影点材料为钽，输送器由鞘芯、鞘管接头、止血阀、手柄和尾柄组成。产品经环氧乙烷灭菌，一次性使用。该产品预期在髂总静脉内使用，用于治疗非血栓性髂静脉压迫综合征。

该产品通过静脉支架近端斜口、喇叭口设计，中段开环设计，支架分段式设计，提高产品性能，以满足临床需求。

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。

（2024-07-11）

Portable Ultrasound Diagnostic System and Disposable Intracardiac Echocardiography Catheter Approved for Marketing

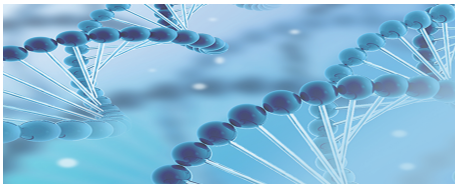
Recently, the two innovative products "Portable Ultrasound Diagnostic System" and "Disposable Intracardiac Echocardiography Catheter" of Shenzhen Sonosemi Medical Co., Ltd. are approved by China NMPA.

The Portable Ultrasound Diagnostic System consists of an ultrasound main unit, a connector and a power adapter. The Disposable Intracardiac Echocardiography Catheter consists of a catheter tip, a steerable tube, an operating handle, and a tail connector, which utilizes the inverse piezoelectric effect to convert the pulsed electrical signals output from the Portable Ultrasound Diagnostic System into ultrasound waves that are emitted into the tissues of the heart cavity, and receives the return signals for transmission to the Portable Ultrasound Diagnostic System, which are converted into digital image signals and then displayed on the monitor.

These two products are used together for ultrasound imaging of the adult heart, major cardiac vessels and intracardiac anatomical structures, with greater depth of detection than similar products, and are the first intracardiac cavity ultrasound imaging system in China.

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

(July 18, 2024)



便携式超声诊断仪和一次性使用心腔内超声成像导管获批上市

近日，国家药品监督管理局批准了深圳市赛禾医疗技术有限公司"便携式超声诊断仪"和"一次性使用心腔内超声成像导管"两个创新产品注册申请。

便携式超声诊断仪由超声主机、连接器和电源适配器组成。一次性使用心腔内超声成像导管由导管头端、可调弯管、操作手柄和尾部连接器组成，利用逆压电效应将便携式超声诊断仪输出的脉冲电信号转变为超声波发射至心脏腔内组织，并接收回波信号传递至便携式超声诊断仪，转为数字图像信号后在显示器上呈现。

上述两个产品配合使用，用于对成人心脏及心脏大血管、心内解剖结构进行超声成像，与同类产品相比，具有更大探测深度,且为国内首个心腔内超声成像系统。

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。

（2024-07-18）

Bioresorbable Rapamycin Target Eluting Coronary Scaffold System Approved for Marketing

Recently, the innovative product "Bioresorbable Rapamycin Target Eluting Coronary Scaffold System" of Shanghai MicroPort Medical (Group) Co., Ltd. is approved by China NMPA.

This product consists of a drug-eluting stent and a delivery system. The stent consists of three parts: the stent body, radiopaque markers, and drug coating. The stent body is made of poly-L-lactic acid (PLLA), with one radiopaque marker at each of the proximal and distal ends of the stent. The rapamycin drug coating is sprayed onto a single side of the outer surface of the stent. The delivery system is a rapid exchange balloon dilatation catheter. This product is sterilized by irradiation and is intended for single use. It is designed to improve the luminal diameter of the coronary artery and is indicated for patients with ischemic heart disease due to primary coronary artery lesions.

The product utilizes a single-sided drug coating technology, where the drug is applied only to the outer surface of the stent through a spot-coating process. This design ensures that the sides and inner surface of the stent struts are free of drug coating, thereby enhancing drug utilization and promoting the endothelialization process within the vessel.

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

(July 30, 2024)

生物可吸收雷帕霉素洗脱冠脉支架系统获批上市

近日，国家药品监督管理局批准了上海微创医疗器械（集团）有限公司"生物可吸收雷帕霉素洗脱冠脉支架系统"创新产品注册申请。

该产品由药物支架和输送系统组成。支架由支架基体、显影标记、药物涂层三部分构成，支架基体材料为左旋聚乳酸（PLLA），在支架近远端各有一个显影标记物，雷帕霉素药物涂层喷涂于支架外表面单面。输送系统为快速交换式球囊扩张导管。该产品经辐照灭菌，一次性使用，改善冠状动脉腔内直径，适用于冠脉原发病变导致的缺血性心脏病患者。

该产品采用了单面药物涂层技术，通过点涂工艺仅在支架外表面涂敷药物，支架杆侧面及内表面无药物涂层，提高了药物利用率，有利于血管内皮化进程。

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。

（2024-07-30）

Renal Denervation RF Generator and Disposable Renal Denervation RF Ablation Catheter Approved for Marketing

肾动脉射频消融仪和一次性使用肾动脉射频消融导管获批上市

Recently, the two innovative products "Renal Denervation RF Generator" and "Disposable Renal Denervation RF Ablation Catheter" of Suzhou SyMap Medical Devices Co., Ltd. are approved by China NMPA.

The Renal Denervation RF Generator consists of a main unit, a foot switch, a hand control, a neutral electrode cable, an equipotential equalization wire and a power cord. The Disposable Renal Denervation RF Ablation Catheter consists of an ablation catheter and a connecting cable. The Renal Denervation RF Generator delivers RF energy through a single channel, which is transmitted via the catheter electrode to the renal artery vascular endothelium, using the current thermal effect to inactivate the sympathetic nerves around the renal artery vasculature, and block the sympathetic nerve's excitatory conduction. Additionally, the catheter electrode can deliver electrical stimulation signals to map the renal artery, identifying sympathetic nerves through changes in blood pressure, thereby enabling selective ablation. This product is indicated for hypertensive patients with a need for reduction in drug use in adjunctive therapy for refractory hypertension and drug-intolerant hypertension. This product is the world's first renal denervation RF ablation system capable of mapping renal nerves. It provides precise ablation positioning for renal sympathetic denervation and offers effective feedback during and after the procedure to evaluate the immediate effects of the denervation, meeting the clinical needs of renal denervation surgery in clinical practice.

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

(August 6, 2024)

近日，国家药品监督管理局批准了苏州信迈医疗器械有限公司"肾动脉射频消融仪"和"一次性使用肾动脉射频消融导管"两个创新产品注册申请。

肾动脉射频消融仪由主机、脚踏开关、手控器、中性电极电缆、等电位均衡导线和电源线组成。一次性使用肾动脉射频消融导管由消融导管和连接电缆组成。肾动脉射频消融仪通过单通道输出射频能量，经过导管电极传递至肾动脉血管内膜，利用电流热效应使肾动脉血管周围交感神经失活，阻断交感神经兴奋传导。同时，导管电极可输出电刺激信号对肾动脉进行标测，通过血压变化识别交感神经，实现选择性消融。该产品适用于难治性高血压和药物不耐受高血压辅助治疗中，对药物使用有减量需求的高血压患者。

该产品为全球首款可标测肾神经的肾动脉射频消融类产品，能够为肾交感神经去除术提供准确消融位置，还可在术中、术后提供有效反馈，以评判肾交感神经去除术的即时效果，满足去肾神经术在临床实践中的需要。

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。

（2024-08-06）

Radio Frequency Renal Ablation Device and Disposable Reticular Renal Denervation RF Ablation Catheter Approved for Marketing

Recently, the two innovative products "Radio Frequency Renal Ablation Device" and "Disposable Reticular Renal Denervation RF Ablation Catheter" of Shanghai Golden Leaf Med Tec Co., Ltd. are approved by China NMPA.

The Radio Frequency Renal Ablation Device consists of a main unit, a foot switch, a main unit connecting cable, a neutral electrode connecting cable, and a power cord. The Disposable Reticular Renal Denervation RF Ablation Catheter consists of a mesh basket stent, an ablation electrode, a protective sheath, a handle, and a connector. These two products are used in conjunction with each other for the adjunctive treatment of patients with refractory hypertension and drug-intolerant hypertension. The Disposable Reticular Renal Denervation RF Ablation Catheter has six electrodes arranged in a spiral pattern, which can effectively improve the ablation efficiency, and the design of mesh basket makes the blood flow not blocked during ablation, which is unique in China and the world. The temperature and impedance measurement and feedback control algorithm used in the Radio Frequency Renal Ablation Device makes the procedure easier to operate. The launch of this product is conducive to the promotion of the clinical application of RF ablation technology, which can further reduce the cost of clinical treatment and benefit more patients with refractory hypertension and drug-intolerant hypertension.

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

(August 6, 2024)

肾动脉射频消融仪及一次性使用网状肾动脉射频消融导管获批上市

近日，国家药品监督管理局批准了上海魅丽纬叶医疗科技有限公司"肾动脉射频消融仪"和"一次性使用网状肾动脉射频消融导管"两个创新产品注册申请。

肾动脉射频消融仪由主机、脚踏开关、主机连接线、中性电极连接线以及电源线组成。一次性使用网状肾动脉射频消融导管由网篮支架，消融电极，保护鞘、手柄、接插件组成。上述两个产品配套使用，用于辅助治疗难治性高血压及药物不耐受的高血压患者。

一次性使用网状肾动脉射频消融导管具有螺旋式排布的六个电极，能够有效提高消融效率，网篮状设计使消融时血流不被阻断，在国内及国际上均属独创。肾动脉射频消融仪采用的温度、阻抗测量及反馈控制算法，使手术操作更加简便。该产品上市有利于射频消融技术的临床应用推广，可进一步降低临床治疗费用，使更多难治性高血压及药物不耐受的高血压患者受益。

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）

Balloon Cryoablation Catheter Approved for Marketing

Recently, the innovative product "Cryoablation Console" of Shanghai Antec Medical Technology Co., Ltd. is approved by China NMPA.

This product consists of a balloon cryoablation catheter, and a manual retractor, and is used in conjunction with a specific cryoablation device for the treatment of adult patients with medically refractory, recurrent, symptomatic paroxysmal atrial fibrillation.

The product features a "32 mm large balloon" and an "8 mm short tip" design, which allows for stable control of refrigerant flow, effective temperature management, and close proximity to the pulmonary vein ostium. This design enables the effective collection of pulmonary vein potentials, ensuring the efficacy of cryoablation. Compared to similar domestic and international products available in China, this technology is pioneering. The market release of this product will further meet the clinical needs in the treatment of paroxysmal atrial fibrillation in China.

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

(August 6, 2024)

球囊型冷冻消融导管获批上市

近日，国家药品监督管理局批准了上海安钛克医疗科技有限公司“球囊型冷冻消融导管”创新产品注册申请。

该产品由球囊型冷冻消融导管、手动回缩器组成，与特定冷冻消融仪联合使用，用于治疗成人患者药物难治性、复发性、症状性的阵发性房颤。

该产品所用“32 mm大球囊”和“8 mm短头”设计，可以稳定控制制冷剂流量，有效控制冷冻温度，且可贴近肺静脉口，有效采集肺静脉电位，从而保证冷冻消融效果。相较于在中国上市的国内、国外同类产品，该技术具有首创性。该产品上市可进一步满足我国在阵发性房颤治疗领域的临床需求。

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。

（2024-04-19）

Prizvalve® Transcatheter Aortic Valve System Approved for Marketing

Recently, the innovative product "Prizvalve® Transcatheter Aortic Valve System" of Shanghai NewMed Medical Co., Ltd. is approved by China NMPA.

This product consists of a transcatheter aortic valve, a transcatheter aortic valve delivery system (including a delivery device and a valve loader), an aortic valve balloon dilatation catheter, a crimping device, and a balloon inflation device.

The Prizvalve® Transcatheter Aortic Valve System is the first domestically produced balloon-expandable transcatheter aortic valve product. 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 product is implanted through the femoral artery into the aortic annulus, replacing the diseased aortic valve and improving the stenosis at the affected site, thereby enhancing cardiac function.

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

(August 14, 2024)

经导管主动脉瓣膜系统获批上市

近日，国家药品监督管理局批准了上海纽脉医疗科技股份有限公司“经导管主动脉瓣膜系统”创新产品注册申请。

该产品由经导管主动脉瓣膜、经导管主动脉瓣膜输送系统（包括输送器和瓣膜载入器）、主动脉瓣球囊扩张导管、压握装置及球囊充压装置组成。

经导管主动脉瓣膜系统是国产首款球囊扩张式经导管主动脉瓣膜产品，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，该产品通过股动脉经导管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。

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。

（2024-08-14）

Vflower® Venous Stent System Approved for Marketing

Recently, the innovative product "Vflower® Venous Stent System" of Shanghai Bluevastec MedTech Co., Ltd. is approved by China NMPA.

This product consists of a venous stent and a delivery system, intended for use in the iliofemoral veins for the treatment of non-thrombotic iliac vein compression syndrome, deep vein thrombosis and post deep vein thrombosis syndrome. The stent is

静脉支架系统获批上市

近日，国家药品监督管理局批准了上海蓝脉医疗科技有限公司“静脉支架系统”创新产品注册申请。

该产品由静脉支架及输送系统组成，预期在髂股静脉内使用，用于治疗非血栓性髂静脉

manufactured using an integrated braiding method, featuring varying mesh densities. The combination of dense and sparse mesh designs effectively meets clinical needs for both support and flexibility.

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

(August 22, 2024)

压迫综合征、深静脉血栓形成及深静脉血栓形成后综合征。其中，支架采用一体化编织方法，具有不同网孔密度，疏密网孔相结合的设计可有效满足临床上对支架的支撑力和柔顺性需求。

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)

Cosmetics

NMPA Announcement on Including the Testing Methods for Azelaic Acid and Its Salts in Cosmetics and Other 5 Testing Methods into the Technical Specification for the Safety of Cosmetics (Edition 2015) (No. 45, 2024)

The National Medical Products Administration (NMPA) has organized to formulate Testing Methods for Azelaic Acid and Its Salts in Cosmetics and other 5 testing methods, which have been reviewed and approved by the Chairman's Meeting of the NMPA's Cosmetic Standardization Technical Committee. These methods are hereby issued.

The Testing Methods for Azelaic Acid and Its Salts in Cosmetics, Testing Methods for Phenacetin in Cosmetics, Testing Methods for Hydroxydecanoic Acid in Cosmetics, and other 3 testing methods are new cosmetic testing methods, which will be included in the Technical Specification for the Safety of Cosmetics (Edition 2015), and will come into force from July 1, 2025.

The Testing Methods for Asbestos in Cosmetics and Testing Methods for Glucuronic Acid and Other 14 Raw Materials in Cosmetics are revised testing methods for cosmetics, which will replace the original testing methods in the Technical Specification for the Safety of Cosmetics (Edition 2015); from July 1, 2025, cosmetic registrations, filings and sampling tests and other related tests should use the above two testing methods issued by this Announcement.

It is hereby notified.

National Medical Products Administration

October 28, 2024

(October 30, 2024)

化妆品

国家药监局关于将化妆品中壬二酸及其盐类的检验方法等5项检验方法纳入化妆品安全技术规范（2015年版）的通告（2024年第45号）

国家药监局组织起草了《化妆品中壬二酸及其盐类的检验方法》等5项检验方法，经国家药监局化妆品标准化技术委员会主任会议审查通过，现予以发布。

《化妆品中壬二酸及其盐类的检验方法》《化妆品中非那西丁的检验方法》《化妆品中羟基癸酸的检验方法》等3项检验方法为新增的化妆品检验方法，纳入《化妆品安全技术规范（2015年版）》，自2025年7月1日起施行。

《化妆品中石棉的检验方法》《化妆品中葡糖醛酸等14种原料的检验方法》为修订的化妆品检验方法，替换《化妆品安全技术规范（2015年版）》中原有检验方法；自2025年7月1日起，化妆品注册、备案及抽样检验等相关检验应当采用本通告发布的上述两个检验方法。

特此通告。

国家药监局

2024年10月28日

(2024-10-30)

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

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