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NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

Headline

NMPA becomes the applicant for PIC/S

In late September 2023, the National Medical Products Administration(NMPA) submitted formal application to the Pharmaceutical Inspection Co-operation Scheme (PIC/S). On Nov 8, 2023, PIC/S sent a letter to NMPA confirming the applicant status.

Following this confirmation, NMPA will strengthen communication and cooperation with the PIC/S, promote itself to become a full member of PIC/S, and take this opportunity to continuously improve the country' s drug inspection system and standards, to constantly enhance its drug inspection quality management system and to steadily promote the development of its inspectors' team, so as to modernize the national drug regulation in China.

(Nov 9, 2023)

头条

国家药品监督管理局成为药品检查合作计划正式申请者

2023年9月下旬，国家药监局向药品检查合作计划（PIC/S）提交了正式申请材料。2023年11月8日，PIC/S致函国家药监局，确认国家药监局正式申请者身份。后续，国家药监局将加强与PIC/S的沟通与合作，积极推进我国早日成为PIC/S正式成员，并以此为契机，持续完善我国药品检查制度和标准，不断健全药品检查质量管理体系，稳步推进检查员队伍建设，提升我国药品监管现代化水平。

（2023-11-09）

Drugs

Deucravacitinib Tablets approved for marketing by China NMPA

Recently, the category 1 innovative product Deucravacitinib Tablets (trade name: Sotyktu) of Bristol Myers Squibb is approve for marketing by China NMPA. This drug is indicated for adults with moderate-to-severe plaque psoriasis through systematic treatment or phototherapy.

Deucravacitinib is a tyrosine kinase 2 (TYK2) inhibitor. The marketing of this drug will provide new treatment options for patients with moderate-to-severe plaque psoriasis.

（Oct 19, 2023）

药品

国家药监局批准氘可来昔替尼片上市

近日，国家药品监督管理局批准百时美施贵宝公司申报的1类创新药氘可来昔替尼片（商品名：颂狄多）上市。该药适用于适合系统治疗或光疗的成年中重度斑块状银屑病患者。

氘可来昔替尼是一种酪氨酸激酶2（TYK2）抑制剂。该药品的上市为中重度斑块状银屑病患者提供了新的治疗选择。

（2023-10-19）

Ritlecitinib Tosylate Capsules approved for marketing

Recently, the Category 1 innovative drug Ritlecitinib Tosylate Capsules (trade name: LITFULO®) of Pfizer Inc. is approved for marketing through priority review and approval procedures by China NMPA. This drug is indicated for treating severe alopecia areata for adults and adolescents 12 years old and older.

Ritlecitinib is a kinase inhibitor, which can irreversibly inhibit Janus kinase 3 (JAK3) and the tyrosine kinase(TEC) family. The marketing of this drug provides new treatment options for patients with severe alopecia areata.

（Oct 19, 2023）

国家药监局批准甲苯磺酸利特昔替尼胶囊上市

近日，国家药品监督管理局通过优先审评程序批准辉瑞公司申报的1类创新药甲苯磺酸利特昔替尼胶囊（商品名：乐复诺）上市。该药适用于12岁及以上青少年和成人重度斑秃患者。

甲苯磺酸利特昔替尼是一种激酶抑制剂，能够不可逆地抑制 JAK3和酪氨酸激酶家族。该药品的上市为重度斑秃患者提供了新的治疗选择。

（2023-10-19）

Published by
China Center for Food and Drug International Exchange

Tongluo Mingmu Capsules approved for marketing by China NMPA

Recently, the Category 1.1 innovative traditional Chinese medicine Tongluo Mingmu Capsules of Shijiazhuang Yiling Pharmaceutical Co., Ltd. is approved for marketing by China NMPA.

This drug has undergone a randomized, double blind, double simulated, parallel controlled multicenter clinical trial of calcium dobesilate capsules. The results of clinical trial study showed that after 12 weeks of treatment, the spot and patch hemorrhage of moderate nonproliferative diabetic retinopathy in the test group was superior to that in the control group. The drug can remove blood stasis and dredge collaterals, replenish qi and nourish yin, stop bleeding and brighten eyes. It is indicated for the symptoms related to blood stasis and obstruction of collaterals in moderate nonproliferative retinopathy caused by type 2 diabetes, and spot and patch hemorrhage of fundus and dryness of eyes caused by deficiency of both qi and yin. The marketing of this drug provides new treatment options for patients with the above-mentioned symptoms.

(Oct 19, 2023)

国家药监局批准中药创新药通络明目胶囊上市

近日，国家药品监督管理局批准了石家庄以岭药业股份有限公司申报的中药1.1类创新药通络明目胶囊上市。

该药品开展了随机、双盲双模拟、羟苯磺酸钙胶囊平行对照的多中心临床试验。临床试验研究结果显示，治疗12周后，中度非增殖性糖尿病视网膜病变的点片状出血试验组优于对照组。该药品化瘀通络、益气养阴、止血明目，用于2型糖尿病引起的中度非增殖性糖尿病视网膜病变血瘀络阻、气阴两虚证所致的眼底点片状出血、目睛干涩等相关症状。该药品的上市为具有上述病证的患者增加一种新的用药选择。

(2023-10-19)

Children's Zibei Xuanfei Syrup approved for marketing

Recently, the Category 1.1 innovative traditional Chinese medicine Children's Zibei Xuanfei Syrup of Jianmin Pharmaceutical Group Co., Ltd. is approved for marketing by China NMPA.

This drug has undergone a randomized, double blind, parallel controlled multi-center clinical trial. The results of clinical trial study showed statistical difference to the placebo control group. This drug is to disperse wind heat, promote lung health, and relieve cough for children with acute trachea-bronchitis with wind-heat invading lung syndrome, with coughing, sweating, throat pain, thirst, thin and yellow tongue coating, and floating and rapid pulse. The marketing of this drug provides new treatment options for relieving cough for children with acute trachea-bronchitis.

(Oct 19, 2023)

国家药监局批准中药创新药小儿紫贝宣肺糖浆上市

近日，国家药品监督管理局批准了健民药业集团股份有限公司申报的中药1.1类创新药小儿紫贝宣肺糖浆上市。

该药品开展了随机、双盲、平行对照的多中心临床试验，临床试验结果显示与安慰剂对照组间比较有统计学差异。该药品疏散风热、宣肺止咳，用于小儿急性支气管炎风热犯肺证的咳嗽，伴咳痰、汗出、咽痛、口渴，舌苔薄黄，脉浮数。该药品的上市为急性支气管炎的咳嗽患儿提供了又一种治疗选择。

(2023-10-19)

Aponermin for Injection approved for marketing by China NMPA

Recently, the Aponermin for Injection (Chinese trade name:沙艾特) of Wuhan HITECK biopharmaceutical Co., Ltd. is approved by China NMPA. This drug, plus thalidomide and dexamethasone, is indicated for the treatment of adult patients with relapsed or refractory Multiple Myeloma after two or more systemic therapies.

The Aponermin for Injection is a Circularly Permuted TRAIL, which can bind and activate death receptor 4 (DR4)/death receptor 5 (DR5) on the surface of tumor cells, triggering intracellular Caspase reactions through exogenous cell apoptosis pathways, thereby exerting anti-tumor effects. The marketing of the drug will provide new treatment options for patients.

(Nov 2, 2023)

国家药监局批准注射用埃普奈明上市

近日，国家药品监督管理局批准武汉海特生物制药股份有限公司申报的注射用埃普奈明（商品名：沙艾特）上市。该药品联合沙利度胺和地塞米松用于既往接受过至少2种系统性治疗方案的复发或难治性多发性骨髓瘤成人患者。

注射用埃普奈明为重组变构人肿瘤坏死因子相关凋亡诱导配体，可结合并激活肿瘤细胞表面的死亡受体4（DR4）/死亡受体5（DR5），通过外源性细胞凋亡途径触发细胞内Caspase级联反应，从而发挥抗肿瘤作用。该药品种的上市为患者提供了更多的治疗选择。

(2023-11-02)

Glofitamab Injection approved with conditions for marketing

Recently, the Glofitamab Injection (trade name: 高罗华/Columvi) of Roche Pharma (Schweiz) AG is approved with conditions by China NMPA. This drug is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, after two or more lines of systemic therapy.

Glofitamab is a bispecific antibody that binds to CD20 expressed on the surface of B cells and to CD3 in the T-cell receptor complex expressed on the surface of T cells, and mediates the formation of an immunological synapses with subsequent T-cell activation and proliferation, secretion of cytokines and release of cytolytic proteins that results in the lysis of CD20-expressing B cells.

The marketing of this drug provides a new treatment option for adult patients with relapsed or refractory diffuse large B-cell lymphoma.

(Nov 8, 2023)

国家药监局附条件批准格菲妥单抗注射液上市

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Roche Pharma (Schweiz) AG申报的格菲妥单抗注射液（商品名：高罗华/Columvi）上市。用于治疗既往接受过至少两线系统性治疗的复发或难治性弥漫大B细胞淋巴瘤成人患者。

格菲妥单抗注射液是一种双特异性抗体，通过与B细胞表面的CD20和T细胞表面的CD3同时结合，介导免疫突触形成，随后引起T细胞活化与增殖、细胞因子分泌和细胞溶解蛋白释放，从而诱导表达CD20的B细胞溶解。

该品种的上市为复发或难治性弥漫大B细胞淋巴瘤成人患者提供了新的治疗选择。

（2023-11-08）

Xianglei Tangzu Cream approved with conditions for marketing

Recently, the natural products Category 1.1 innovative drug Xianglei Tangzu Cream (Fespixon Cream) of Oneness Biotech Co., Ltd. was approved for marketing with conditions by China NMPA. This drug is used for treating Wagner grade 1 diabetic foot ulcer (DFU) with wound cross-sectional area less than 25cm2 after debridement. The marketing of this drug provides a new treatment option for patients with Wagner grade 1 DFU.

(Nov 14, 2023)

国家药监局附条件批准天然药物创新药香雷糖足膏上市

近日，国家药品监督管理局附条件批准了合一生技股份有限公司申报的天然药物1.1类创新药香雷糖足膏上市。用于清创后创面截面积小于25cm2的Wagner 1级糖尿病足部伤口溃疡。该品种的上市为Wagner–1级糖尿病足患者提供了新的治疗选择。

（2023-11-14）

Vebreltinib Enteric Capsules Approved with Conditions for Marketing

Recently, the Category 1 innovative drug Vebreltinib Enteric Capsules of Beijing Pearl Biotechnology Limited Liability Company was approved for marketing with conditions by China NMPA. This drug is indicated for the treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) patients with mesenchymal epithelial transition factor (MET) exon 14 mutation.

Vebreltinib is a tyrosine kinase inhibitor of cell mesenchymal epithelial transition factor (c-MET) receptor that can inhibit the proliferation of tumor cells with high c-MET expression. The marketing of this drug provides a new treatment option for NSCLC patients with MET exon 14 mutation.

(Nov 16, 2023)

国家药监局附条件批准伯瑞替尼肠溶胶囊上市

近日，国家药品监督管理局附条件批准北京浦润奥生物科技有限责任公司申报的1类创新药伯瑞替尼肠溶胶囊上市。该药适用于治疗具有间质–上皮转化因子（MET）外显子14跳变的局部晚期或转移性非小细胞肺癌患者。

伯瑞替尼是一种细胞–间质上皮转化因子(c–MET)受体酪氨酸激酶抑制剂，可抑制c–MET高表达肿瘤细胞的增殖。该药品的上市为MET外显子14跳变非小细胞肺癌患者提供了新的治疗选择。

（2023-11-16）

Children's Chiqiao Qingre Syrup approved for marketing

Recently, the Category 2.2 moidfied new traditional Chinese medicine Children's Chiqiao Qingre Syrup of Jumpcan Pharmaceutical Group Co., Ltd. is approved for marketing by China NMPA. It is a pediatric drug with highly increased compliance after the modification of dosage form.

This drug is to dispel wind and release the exterior, clear heat and promote stagnation, and is suitable for children with wind heat and cold stagnation syndrome. Indications include fever, cough, nasal congestion and runny nose, sore throat, anorexia and thirst, bloating in the epigastric region, constipation or sour and foul smelling stool, and deep-colored urine. The marketing of this drug provides new treatment choice for children with wind heat and cold stagnation syndrome.

(Nov 17, 2023)

国家药监局批准中药改良型新药小儿豉翘清热糖浆上市

近日，国家药品监督管理局批准了济川药业集团有限公司申报的中药2.2类改良型新药小儿豉翘清热糖浆上市。该品种为儿童用药，剂型改良后顺应性明显提高。

该药品疏风解表，清热导滞，用于小儿风热感冒夹滞证，症见发热咳嗽、鼻塞流涕、咽红肿痛、纳呆口渴、脘腹胀满，便秘或大便酸臭、溲黄。该药品的上市为小儿风热感冒夹滞证患儿提供了又一种治疗选择。

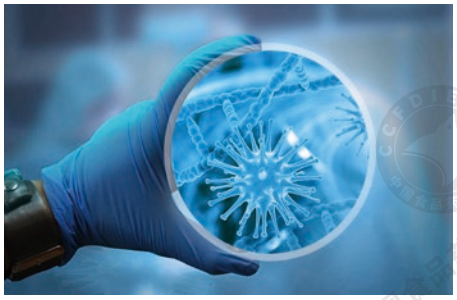
(2023-11-17)

Atilotrelvir Tablets/Ritonavir Tablets approved with conditions

Recently, the Category 1 innovative drug Atilotrelvir Tablets/Ritonavir Tablets (co-packaged) (Chinese trade name: 泰中定) of Fujian Guangsheng Zhonglin Biotechnology Co., Ltd. was approved with conditions by China NMPA through the emergency review and approval procedure in accordance with the relevant provisions of special review and approval prescribed in the Drug Administration Law. This is an oral small-molecule drug for the treatment of SARS-CoV-2(COVID-19) infection, indicated for treating adult patients with mild to moderate COVID-19 infection. The patients should use the drug by strictly following the package insert under doctors' guidance.

The MAH is asked by NMPA to complete relevant research works of the conditional requirements within a time limit, and submit the follow-up research results in time.

(Nov 24, 2023)



国家药监局附条件批准新冠病毒感染治疗药物阿泰特韦片/利托那韦片组合包装上市

近日，国家药监局根据《药品管理法》相关规定，按照药品特别审批程序，进行应急审评审批，附条件批准福建广生中霖生物技术有限公司申报的1类创新药阿泰特韦片/利托那韦片组合包装（商品名称：泰中定）上市。该药品为口服小分子新冠病毒感染治疗药物，用于治疗轻型、中型新型冠状病毒感染（COVID-19）的成年患者。患者应在医师指导下严格按说明书用药。

国家药监局要求上市许可持有人继续开展相关研究工作，限期完成附条件的要求，及时提交后续研究结果。

(2023-11-24)

Dimdazenil Capsules approved for marketing by China NMPA

Recently, the Category 1 innovative drug Dimdazenil Capsules of Zhejiang Jingxin Pharmaceutical Co., Ltd. was approved for marketing by China NMPA. This drug is indicated for short-term treatment for insomnia patients.

Dimdazenil is a benzodiazepine drug that is a partial positive allosteric modulator for γ-aminobutyric acid (GABAA) receptor. It exerts the effect of promoting sleep by partially activating GABAA receptors. The marketing of this drug provides a new treatment option for insomnia patients.

(Nov 29, 2023)

国家药监局批准地达西尼胶囊上市

近日，国家药品监督管理局批准浙江京新药业股份有限公司申报的1类创新药地达西尼胶囊上市。该药适用于失眠患者的短期治疗。

地达西尼属于苯二氮䓬类药物，是γ-氨基丁酸A型（GABAA）受体的部分正向别构调节剂，通过部分激活GABAA受体，产生促进睡眠的作用。该药品的上市为失眠患者提供了新的治疗选择。

(2023-11-29)

Recombinant Humanized Type III Collagen Solution Approved

Recently, the innovative product Recombinant Humanized Type III Collagen Solution for injection of Shanxi Jinbo Bio-pharmaceutical Co., Ltd. is approved by China NMPA.

This product is a colorless or almost white liquid composed of recombinant humanized type III collagen and 0.9% physiological saline. It is applied for filling facial dermal tissue to correct dynamic wrinkles in the forehead (including eyebrow lines, forehead lines, and fishtail lines). The recombinant collagen biomaterial used in this product can be assembled into collagen fiber networks, which support cells and tissues in dermal collapse, and physically fills those areas. The immunogenicity risk of the product is controllable, as the substances will gradually be decomposed and absorbed by the collagenase after injection.

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

(Aug 16, 2023)

Magnetic Resonance Imaging System approved for marketing

Recently, the innovative product Magnetic Resonance Imaging System of Wuhan Verlmagin Medical Technology Co., Ltd is approved by China NMPA.

This product is composed of magnets, an examination table, spectrometer, gradient power amplifier, RF power amplifier, xenon RF power amplifiers, power distribution system, physiological signal gating unit, etc., with independent intellectual property rights. This product adds xenon nuclear imaging function to the conventional magnetic resonance imaging system, which can enable non-invasive and radiation-free distribution of gas in the lungs. It is the first domestic magnetic resonance imaging system that can be used for pulmonary gas imaging.

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

(Aug 16, 2023)

Cryoablation Equipment and Balloon Cryoablation Catheter Approved for Marketing

Recently, the innovative products Cryoablation Equipment and Balloon Cryoablation Catheter of Cryofocus Medtech (Shanghai) Co., Ltd. are approved by China NMPA.

The Cryoablation Equipment consists of a freezing unit, a vacuum system, a cryogenic working fluid delivery circuit, and a control system. On the other hand, the Balloon Cryoablation Catheter consists of a device connection part, an operation control part, and a blood contact part. These two products are used in combination in medical institutions for the treatment of drug-refractory, recurrent, symptomatic, and paroxysmal atrial fibrillation.

During the treatment, the Cryoablation Equipment delivers nitrogen gas to the inner lumen of the balloon after it is cooled by a heat exchanger, enabling the balloon to make contact with the tissue at a low temperature. Additionally, it dynamically adjusts the pressure and flow of the freezing medium based on the temperature feedback from the catheter to maintain the surface temperature of

注射用重组Ⅲ型人源化胶原蛋白溶液获批上市

近日，国家药品监督管理局批准了山西锦波生物医药股份有限公司生产的注射用重组Ⅲ型人源化胶原蛋白溶液创新产品注册申请。

该产品为无色或类白色液体，由重组Ⅲ型人源化胶原蛋白和0.9%的生理盐水组成，适用于面部真皮组织填充以纠正额部动力性皱纹（包括眉间纹、额头纹和鱼尾纹）。该产品采用的重组胶原蛋白生物材料可组装成胶原蛋白纤维网，对细胞、组织起支撑作用，使皱纹塌陷的部位得到物理填充。产品免疫原性风险可控，注射后会逐渐被体内胶原蛋白酶分解吸收。

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。

（2023-08-16）

磁共振成像系统获批上市

近日，国家药品监督管理局批准了武汉中科极化医疗科技有限公司生产的磁共振成像系统创新产品注册申请。

该产品由磁体、检查床、谱仪、梯度功率放大器、射频功率放大器、氙射频功率放大器、配电系统、生理信号门控单元等组成，拥有自主知识产权。该产品在常规磁共振成像系统基础上增加氙核成像功能，可使气体无侵入、无辐射地在肺部分布，为我国首款可用于肺部气体成像的磁共振成像系统。

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。（2023-08-16）

冷冻消融设备和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康沣生物科技（上海）股份有限公司生产的“冷冻消融设备”和“球囊型冷冻消融导管”创新产品注册申请。

“冷冻消融设备”由冷冻装置、真空系统、低温工质输送回路和控制系统组成。“球囊型冷冻消融导管”由设备连接部件、操作控制部件和血液接触部件组成。上述两个产品在医疗机构配套使用，用于药物难治性、复发性、症状性、阵发性房颤的治疗。

治疗过程中，“冷冻消融设备”可将氮气经热交换器冷却后输送至球囊内腔，使与组

the balloon within the specified range. Simultaneously, the vacuum pump of the equipment continuously extracts air from the outer pipeline of the catheter, achieving a high vacuum insulation state in the outer pipeline of the product, ensuring the safety of the non-ablation area and therefore improving the safety of the surgery.

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

(Aug 24, 2023)

织接触的球囊产生低温，并通过导管反馈的温度，动态调控冷冻介质的压力和流量，将球囊表面温度维持在规定范围内。同时，该设备真空泵持续抽取导管外层管路内的空气，使产品外层管路达到高真空的隔热状态，确保非消融区域的安全，提高了手术安全性。

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。

（2023-08-24）

Proton Therapy System Approved for Marketing

Recently, the innovative product Proton Therapy System of Varian Medical Systems Inc. is approved by China NMPA.

This product is composed of proton accelerator subsystem and treatment subsystem. The proton accelerator subsystem consists of 3 major components: main proton accelerator system, energy selection system and beam transport system. The treatment subsystem contains 3 treatment room, including a 360-degree rotating beam treatment system and Treatment Planning System. The product provides radiation therapy with proton beams for the treatment of solid malignant tumors for all organs and several benign tumors, with specific indications to be determined by clinicians according to the actual situation.

This product is the first approved proton therapy system with superconducting cyclotron and 360-degree rotating gantry. With these technologies, this product is compact in structure with multi-angle treatment function. It can effectively shorten the treatment time for patients while ensuring effectiveness.

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

(Nov 1, 2023)

质子治疗系统获批上市

近日，国家药品监督管理局批准了瓦里安医疗系统粒子治疗有限公司生产的“质子治疗系统”创新产品注册申请。

该产品由加速器子系统和治疗子系统组成。加速器子系统包括主加速器系统、能量选择系统和射束传输系统，治疗子系统含3个治疗室，包括360度旋转束治疗系统和治疗计划系统。该产品提供质子束进行放射治疗，适用于治疗全身实体恶性肿瘤及某些良性疾病，具体适应症由临床医师根据实际情况确定。

该产品是首台获批的采用超导回旋加速器技术和360度旋转机架的质子治疗系统。上述技术确保了产品结构紧凑，并可以实现多角度治疗。同时，该产品在保证患者治疗效果的前提下，能够有效缩短患者治疗时间。

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。

（2023-11-01）

Single Photon Emission and X-ray Computed Tomography Imaging System Approved for Marketing

Recently, the innovative product Single Photon Emission and X-ray Computed Tomography Imaging System of Beijing Novel Medical Equipment Ltd. is approved by China NMPA.

This product consists of a single photon emission computed tomography (SPECT) host (including two SPECT detectors), CT host frame, examination bed, PDU server, acquisition client workstation, SPECT acquisition server workstation, CT acquisition reconstruction workstation, image processing workstation, patient positioning monitor, SPECT collimator, etc.

This product is clinically used for imaging examination and evaluation of tumors, cardiovascular system, urinary system, and neurological diseases, and its SPECT part can also enable imaging separately. As the first domestic multi-angle, dual-probe, and general-purpose SPECT/CT all-in-one machine, this product not only fills the domestic gap, but also is on par with international advanced standards in various performance indicators. Its clinical application can further improve the diagnostic ability of tumors, ischemic heart disease, and kidney diseases in China, conducive to save clinical resources and reduce medical costs.

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

(Nov 8, 2023)

单光子发射及X射线计算机断层成像系统获批上市

近日，国家药品监督管理局批准了北京永新医疗设备有限公司的“单光子发射及X射线计算机断层成像系统”创新产品注册申请。

该产品由单光子发射计算机断层扫描系统(SPECT)主机（含两个SPECT探测器）、CT主机架、检查床、PDU服务器、采集客户端工作站、SPECT采集服务器工作站、CT采集重建工作站、影像处理工作站、患者定位监视器、SPECT准直器等组成。

该产品临床用于肿瘤、心血管系统、泌尿系统、神经系统疾病的影像学检查及评估，其SPECT部分还可单独成像。作为国产首台可变角、双探头、通用型SPECT/CT一体机，该产品不仅填补了国内空白，而且各项性能指标达到国际先进水平，其临床应用可进一步提升我国肿瘤、缺血性心脏病、肾脏疾病的诊断能力，有助于节省临床资源、降低医疗成本。

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。（2023-11-08）

Additive Manufacturing Matching Knee Prosthesis Approved for Marketing

Recently, the innovative product Additive Manufacturing Matching Knee Prosthesis of Naton Biotechnology (Beijing) Co., Ltd. is approved by China NMPA.

This product consists of a femoral condylar prosthesis, a tibial tray prosthesis, and a meniscus prosthesis. The femoral condylar prosthesis and tibial tray prosthesis is constructed from cobalt-chromium-molybdenum powder by laser additive manufacturing, while the meniscus prosthesis is constructed from ultra-high molecular weight polyethylene. Notably, this product adopts a personalized design of total knee prosthesis, featuring a bionic design of the joint surface that allows for the reconstruction of normal patellofemoral joint movement. With its application in knee prosthesis replacement, in combination with bone cement, this product is tailored for patients with osteoarthritis and those in special needs. Moreover, it is capable of achieving satisfactory coverage on each osteotomy plane, effectively solving the problems of mismatch and over-coverage. The marketing of this product will provide a new treatment option for patients.

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

(Nov 17, 2023)

增材制造匹配式人工膝关节假体获批上市

近日，国家药品监督管理局经审查，批准了纳通生物科技（北京）有限公司“增材制造匹配式人工膝关节假体”创新产品注册申请。

该产品包含股骨髁假体、胫骨托假体、半月板假体。股骨髁假体和胫骨托假体由钴铬钼粉材经激光增材制造而成，半月板假体由超高分子量聚乙烯材料制成。该产品采用全膝关节假体的个性化设计，其关节曲面仿生设计能够重建正常股髌关节运动功能。

该产品与骨水泥配合使用，适用于膝关节假体置换，骨关节炎患者和特殊患者均可使用。产品能够在各截骨面上实现良好覆盖，有效解决了不匹配和过覆盖问题。产品的上市将为患者治疗提供新的选择。

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。（2023-11-17）

Disposable Intracardiac Ultrasound Diagnostic Catheter Approved for Marketing

Recently, the innovative product Disposable Intracardiac Ultrasound Diagnostic Catheter of Jiangsu Tingsn Technology Co., Ltd. is approved by China NMPA.

This product consists of a catheter, an operating handle, and a connector. In conjunction with the color ultrasound diagnostic instrument manufactured by the company, it enables medical institutions to perform ultrasound imaging of the heart and the great vessels, as well as intracardiac anatomical structures.

By harnessing high-frequency ultrasound, this catheter provides two-dimensional imaging and three-dimensional modeling of the heart, enabling accurate, rapid, and efficient ultrasound surgery. It also offers real-time, precise anatomical images and simultaneous monitoring of hemodynamic changes, enhancing the visualization of cardiac tissue characteristics and fine structures and real-time monitoring. This allows for the prompt detection of surgery-related complications, thus maximizing surgical safety. The marketing of this product is conducive to reducing the cost of clinical treatment and ultimately bringing benefits to more patients.

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

(Nov 29, 2023)

一次性使用心腔内超声诊断导管获批上市

近日，国家药品监督管理局批准了江苏霆升科技有限公司生产的“一次性使用心腔内超声诊断导管”创新产品注册申请。

该产品由导管主体、操作手柄和连接器组成，配合该公司生产的便携式彩色超声诊断仪，适用于医疗机构开展心脏及心脏大血管、心内解剖结构的超声成像。

该产品通过高频超声波对心脏部位进行二维成像和三维建模，能够准确、快速、高效的实现超声手术。该产品可提供实时精确的解剖图像，同时监测血流动力学变化，对于心脏组织特征及细微结构的显示较好，能够实时监测，及时发现与手术相关的并发症，最大限度保障手术安全。该产品的上市有利于降低临床治疗费用，使更多患者受益。

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。（2023-11-29）

Transcatheter Mitral Valve Repair System approved for marketing

Recently, the innovative product Transcatheter Mitral Valve Repair System of Hangzhou Valgen MedTech Co., Ltd. is approved by China NMPA.

This product consists of two components including a guide sheath and a mitral valve clamping system. Among them, the mitral valve clamping system includes a mitral valve clamp and a delivery system. The elastic center sealing network structure of the mitral

经导管二尖瓣夹系统获批上市

近日，国家药品监督管理局经审查，批准了杭州德晋医疗科技有限公司“经导管二尖瓣夹系统”创新产品注册申请。

该产品由导引鞘、二尖瓣夹系统两个部

valve clamp can increase the sealing performance, reduce residual leaflets at the center, and reduce the clamping force of the valve leaflets; At the same time, the mitral valve clamp also has functions such as individual capture of valve leaflets and repeated positioning capture, which can improve operational accuracy and reduce the risk of mitral valve clamp detachment and valve leaflet perforation.

This product is suitable for patients with degenerative mitral regurgitation (MR≥3+) who have been assessed by the cardiac team as having a high risk of surgical intervention and have a suitable anatomical structure of the mitral valve. The launch 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.

(Nov 30, 2023)

件组成。其中，二尖瓣夹系统包含二尖瓣夹和输送系统，其二尖瓣夹的弹性中心封堵网结构，可以增加夹合密封性，降低中心残余反流，降低瓣叶夹合力；同时，二尖瓣夹还具有单独捕获瓣叶、重复定位抓捕等功能设计，可以提高操作精度，减少二尖瓣夹脱落及瓣叶穿孔的风险。

该产品适用于经心脏团队评估后，认为存在外科手术高风险，且二尖瓣瓣膜解剖结构适合的退行性二尖瓣反流（MR≥3+）患者。该产品的上市将为临床治疗提供更多的选择。

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。

（2023-11-30）

Gelatin Polycaprolactone Layered Gingival Repair Membrane approved for marketing

Recently, the innovative product Gelatin Polycaprolactone Layered Gingival Repair Membrane of Neo Modulus (Suzhou) Medical Sci-Tech Co., Ltd. is approved by China NMPA.

This product is a white film with a fiber layer structure. It is a three-layer composite film made of gelatin and polycaprolactone through electrospinning technology. The upper and lower layers are gelatin, and the middle layer is polycaprolactone, without distinguishing between the front and back sides. Among them, the gelatin fiber layer comes into contact with the wound surface, assisting in the widening of keratinized gingiva; The polycaprolactone fiber layer increases the mechanical strength of the composite film, making it easy to operate and remove without direct contact with human tissues.

This product is suitable for widening the keratinized gingiva and deepening the vestibular sulcus in the oral cavity. The appropriate model can be selected based on the expected repair area of the applicable area. The marketing of the product will provide new treatment options for patients.

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

(Nov 30, 2023)

明胶–聚己内酯分层牙龈修复膜获批上市

近日，国家药品监督管理局经审查，批准了诺一迈尔（苏州）医学科技有限公司“明胶–聚己内酯分层牙龈修复膜”的创新产品注册申请。

该产品为白色膜状，纤维层结构，是由明胶和聚己内酯经静电纺丝技术制成的三层复合膜，上下两层为明胶，中间层为聚己内酯，不区分正反面。其中，明胶纤维层与创面接触，协助角化龈增宽；聚己内酯纤维层为复合膜增加机械强度，方便操作及取出，不与人体组织直接接触。

该产品适用于口腔角化龈增宽，加深前庭沟，可根据适用部位预期修复面积大小选择合适型号。产品的上市将为患者治疗提供新的选择。

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。

（2023-11-30）

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

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