2024 Volume 4

NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

Headline

NMPA Re-elected as a Member of the ICH Management Committee

On June 4, 2024, the plenary session of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) was held in Fukuoka, Japan, at which the National Medical Products Administration (NMPA) was elected as a member of the ICH Management Committee for the third time. ICH is an international organization that formulates and coordinates the technical standards for the R&D and registration of new drugs in different countries. The NMPA joined the ICH in 2017 and was elected as a member of the ICH Management Committee twice in 2018 and 2021. Being re-elected as a member of the ICH Management Committee for the third time this year indicates that China is in line with the international rules in new drug R&D and registration technical standards, and that the internationalization process of drug administration has been recognized internationally. It also signifies a significant enhancement of China's voice in international organizations.

Going forward, the NMPA will adhere to the development directions of being scientific, legalized, internationalized, and modernized. It will actively participate in the international coordination of ICH topics, continue to promote the alignment of domestic drug review standards to international ones, and make every effort to boost the new drug R&D in China, driving China's transformation from a big pharmaceutical manufacturing country to a powerful one.

(June 20, 2024)

头条

国家药监局连任国际人用药品注册技术协调会管委会成员

2024年6月4日，国际人用药品注册技术协调会（ICH）全体会议在日本福冈召开，会上，国家药监局第三次当选ICH管委会成员。ICH是国际上不同国家间新药研发、注册技术标准的制定和协调组织，国家药监局于2017年加入ICH，2018年、2021年两次当选为ICH管委会成员。今年第三次连任ICH管委会成员，表明我国在新药研发及注册技术标准方面与国际规则接轨，药品监管国际化进程方面得到国际认可，我国在国际组织中的话语权也得到显著增强。

下一步，国家药监局将坚持科学化、法治化、国际化、现代化的发展方向，积极参加ICH议题国际协调、持续推动药品审评标准与国际接轨，全力促进我国新药研发，推动我国由制药大国向制药强国迈进。

(2024-06-20)

Drugs

Sulbactam Sodium for Injection/Durlobactam Sodium for Injection (co-packaged) Approved for Marketing by China NMPA

Recently, the Category 1 innovative drug, Sulbactam Sodium for Injection/Durlobactam Sodium for Injection (co-packaged) (trade name: 鼎优乐/XACDURO) of Entasis Therapeutics, Inc. is approved for marketing through the priority review and approval procedure by China NMPA. This drug is indicated for the treatment of hospital acquired bacterial pneumonia (HABP), ventilator associated bacterial pneumonia (VABP) in patients 18 years of age and older caused by susceptible isolates of Acinetobacter baumannii-calcifaciens acetate complex.

This product is a combination packaged product containing both sulbactam sodium for injection and durlobactam sodium for injection. Sulbactam is a β-lactam antimicrobial and Ambler A serine β-lactamase inhibitor while dulobactam is a diazabicyclooctane, non-β-lactam β-lactamase inhibitor that protects sulbactam from degradation by β-lactamase. The marketing of

药品

国家药监局批准注射用舒巴坦钠/注射用度洛巴坦钠组合包装上市

近日，国家药品监督管理局通过优先审评审批程序批准Entasis Therapeutics, Inc.申报的1类创新药注射用舒巴坦钠/注射用度洛巴坦钠组合包装（商品名：鼎优乐/XACDURO）上市。该药品用于治疗18岁及以上患者由鲍曼-醋酸钙不动杆菌复合体敏感分离株所致医院获得性细菌性肺炎（HABP）、呼吸机相关性细菌性肺炎（VABP）。

本品是含注射用舒巴坦钠和注射用度洛巴坦钠的组合包装产品。舒巴坦是一种β-内酰胺类抗菌药物和 Ambler A类丝氨酸β-内酰胺酶抑制剂，度洛巴坦是一种二氮杂二环辛烷、非

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China Center for Food and Drug International Exchange

this drug provides a new treatment option for patients with HABP and VABP caused by susceptible isolates of the Acinetobacter baumannii-calcium acetate complex.

(May 20, 2024)

β-内酰胺类的β-内酰胺酶抑制剂，可保护舒巴坦不被β-内酰胺酶降解。该药品上市为由鲍曼-醋酸钙不动杆菌复合体敏感分离株所致医院获得性细菌性肺炎、呼吸机相关性细菌性肺炎患者提供了新的治疗手段。

（2024-05-20）

Ivonescimab Injection Approved for Marketing by China NMPA

Recently, the Ivonescimab Injection (trade name: 依达方) of Akeso Inc. is approved for marketing through the priority review and approval procedure by China NMPA. This product, in combination with pemetrexed and carboplatin, is indicated for the treatment of patients with locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) who are positive for EGFR gene mutation and have progressed after treatment with epidermal growth factor receptor (EGFR) tyrosine kinase inhibitors (TKI).

As a humanized bispecific antibody of IgG1 subtype binding human vascular endothelial growth factor-A (VEGF-A) and programmed death protein-1 (PD-1), Ivonescimab Injection exerts anti-tumor activity by simultaneous binding to VEGF-A and PD-1 to competitively block the interaction of VEGF-A and PD-1 with their ligands. The marketing of this drug provides a new treatment option for patients.

(May 24, 2024)

国家药监局批准依沃西单抗注射液上市

近日，国家药品监督管理局通过优先审评审批程序批准康方赛诺医药有限公司申报的依沃西单抗注射液（商品名：依达方）上市。本品联合培美曲塞和卡铂，用于经表皮生长因子受体（EGFR）酪氨酸激酶抑制剂（TKI）治疗后进展的EGFR基因突变阳性的局部晚期或转移性非鳞状非小细胞肺癌（NSCLC）患者的治疗。

依沃西单抗注射液是一种靶向结合人血管内皮生长因子-A（VEGF-A）和程序性死亡蛋白-1（PD-1）的IgG1亚型人源化双特异性抗体，可同时与VEGF-A、PD-1结合，竞争性阻断VEGF-A、PD-1与其配体的相互作用，发挥抗肿瘤活性。该品种的上市为患者提供了新的治疗选择。

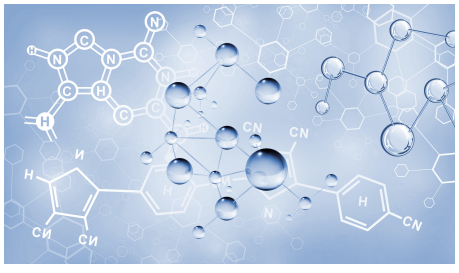
（2024-05-24）

Rilertinib Mesylate Tablets Approved for Marketing by China NMPA

Recently, the Category 1 innovative drug Rilertinib Mesylate Tablets (trade name: 圣瑞沙) of Nanjing Sanhome Pharmaceutical Limited Company is approved for marketing by China NMPA. This drug is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) who have experienced disease progression during or after previous treatment with epidermal growth factor receptor (EGFR) tyrosine kinase inhibitors (TKI) and have been confirmed by testing to be positive for the EGFR T790M mutation.

Rilertinib is an EGFR kinase inhibitor. The marketing of this drug provides a new treatment option for NSCLC patients.

(June 17, 2024)



国家药监局批准甲磺酸瑞厄替尼片上市

近日，国家药品监督管理局批准南京圣和药业股份有限公司申报的1类创新药甲磺酸瑞厄替尼片（商品名：圣瑞沙）上市，该药适用于既往经表皮生长因子受体（EGFR）酪氨酸激酶抑制剂（TKI）治疗时或治疗后出现疾病进展，并且经检测确认存在EGFR T790M突变阳性的局部晚期或转移性非小细胞肺癌（NSCLC）成人患者的治疗。

瑞厄替尼是一种EGFR激酶抑制剂，该药品的上市为非小细胞肺癌患者提供了新的治疗选择。

（2024-06-17）

Envonalkib Citrate Capsules Approved for Marketing by China NMPA

Recently, the Category 1 innovative drug Envonalkib Citrate Capsules (trade name: 安洛晴) of Chia Tai Tianqing Pharmaceutical Group Co., Ltd. is approved for marketing by China NMPA. This drug is indicated for the treatment of patients with ALK-positive locally

国家药监局批准枸橼酸依奉阿克胶囊上市

近日，国家药品监督管理局批准正大天晴药业集团股份有限公司申报的1类创新药枸橼酸依奉阿克胶囊（商品名：安洛晴）上市，该

advanced or metastatic non-small cell lung cancer (NSCLC) who have not received treatment with anaplastic lymphoma kinase (ALK) inhibitors.

Envonalkib Citrate Capsule is a tyrosine kinase receptor inhibitor. The marketing of this drug provides a new treatment option for NSCLC patients.

(May 20, 2024)

药适用于未经过间变性淋巴瘤激酶（ALK）抑制剂治疗的ALK阳性的局部晚期或转移性非小细胞肺癌（NSCLC）患者的治疗。

枸橼酸依奉阿克胶囊是一种酪氨酸激酶受体抑制剂，该药品的上市为非小细胞肺癌患者提供了新的治疗选择。

（2024-05-20）

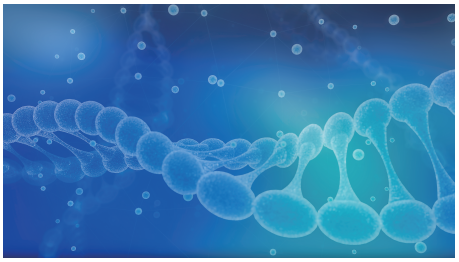
Insulin icodec Injection Approved for Marketing by China NMPA

Recently, the insulin icodec injection (trade name: 诺和期/Awiqli) of Novo Nordisk A/S is approved for marketing by China NMPA. It is indicated for the treatment of adults with type 2 diabetes.

As a novel long-acting insulin analog, insulin icodec can reversibly bind to albumin, form a reservoir in the circulatory system and release slowly and continuously. The hypoglycemic effect of insulin icodec was evenly distributed over a one-week administration interval, and the duration of the hypoglycemic effect could be covered over a one-week period at clinically relevant dosage.

The marketing of this drug provides a new treatment option for adult patients with type 2 diabetes.

(June 24, 2024)



国家药监局批准依柯胰岛素注射液上市

近日，国家药品监督管理局批准丹麦诺和诺德公司（Novo Nordisk A/S）申报的依柯胰岛素注射液（商品名：诺和期/Awiqli）上市，用于治疗成人2型糖尿病。

依柯胰岛素是一种新型长效胰岛素类似物，可与白蛋白可逆性结合，在循环系统形成储库并缓慢持续释放。在一周给药间隔内，依柯胰岛素降糖作用分布均匀，并且在临床相关剂量下降糖作用时间可覆盖一周。

该品种的上市为成人2型糖尿病患者提供了新的治疗选择。

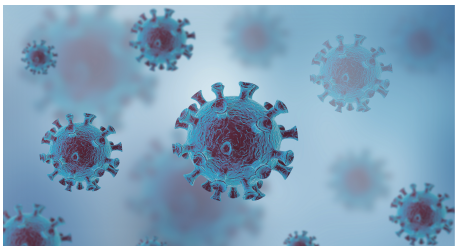
（2024-06-24）

Cofrogliptin Tablets Approved for Marketing by China NMPA

Recently, the Category 1 innovative drug Cofrogliptin Tablets (trade name: 倍长平) of Haisco Pharmaceutical Group Co., Ltd. is approved for marketing by China NMPA. It is indicated for improving the blood glucose control for adult patients with type 2 diabetes.

Cofrogliptin, a dipeptidyl peptidase 4 (DPP-4) inhibitor, can inhibit DPP-4 activity and increase the plasma concentration of glucagon-like peptide-1 (GLP-1) and glucose dependent insulin-like polypeptide (GIP) to reduce blood glucose by increasing insulin release in a glucose dependent manner and decreasing glucagon. The marketing of this drug provides a new treatment option for adult patients with type 2 diabetes.

(June 24, 2024)



国家药监局批准考格列汀片上市

近日，国家药品监督管理局批准海思科医药集团股份有限公司申报的1类创新药考格列汀片（商品名：倍长平）上市，该药适用于改善成人2型糖尿病患者的血糖控制。

考格列汀是二肽基肽酶4（DPP-4）抑制剂，可抑制DPP-4活性，增加胰高血糖素样肽-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，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。

（2024-06-24）

Golidocitinib Capsules Approved with Conditions for Marketing by China NMPA

Recently, the Category 1 innovative drug Golidocitinib capsule (trade name:高瑞哲) of Dizal (Jiangsu) Pharmaceuticals Co. Ltd. is approved with condition for marketing through the priority review and approval procedure by China NMPA. This drug is indicated as a single

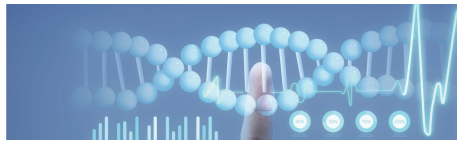
国家药监局附条件批准戈利昔替尼胶囊上市

近日，国家药品监督管理局通过优先审评审批程序，附条件批准迪哲（江苏）医药股份有限公司申报的1类创新药戈利昔替尼胶囊

agent for adult patients with relapsed or refractory peripheral T-cell lymphoma (r/r PTCL) who have received at least one line of systemic treatment.

As a JAK1 inhibitor, Golidocitinib inhibits tumor cell proliferation by blocking the Janus kinase/signal transducer and activator of transcription (JAK/STAT) protein pathway and inhibiting STAT3 phosphorylation and corresponding signaling in tumor cells. The marketing of this drug provides a new treatment option for adult patients with r/r PTCL.

(June 24, 2024)



（商品名：高瑞哲）上市，该药单药适用于既往至少接受过一线系统性治疗的复发或难治的外周T细胞淋巴瘤（r/r PTCL）成人患者。

戈利昔替尼是一种JAK1抑制剂，可通过阻断JAK/STAT（Janus激酶/信号传导及转录激活蛋白）通路，抑制肿瘤细胞中STAT3磷酸化及相应信号传导，从而抑制肿瘤细胞增殖。该药品的上市为外周T细胞淋巴瘤成人患者提供了新的治疗选择。

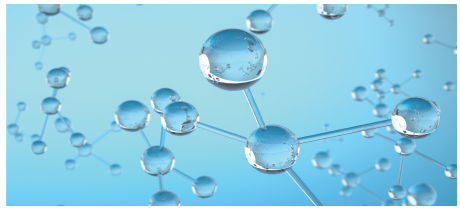
（2024-06-24）

Bevifibatide Citrate Injection Approved for Marketing by China NMPA

Recently, the he Category 1 innovative drug Bevifibatide Citrate Injection (trade name: 贝塔宁/BETAGRIN) of Bio-Thera Solutions, Ltd. is approved for marketing by China NMPA. This drug is indicated for patients with acute coronary syndrome who undergo percutaneous coronary intervention (including intracoronary stenting) to reduce the risk of acute occlusion, and in-stent thrombosis, as well as the occurrence of no reflow and slow flow.

Bevifibatide citrate, a peptide platelet GPIIb/IIIa (also known as αIIbβ3) receptor antagonist, inhibits platelet aggregation by preventing the binding of fibrinogen, von Willebrand factor, and other adhesive ligands from binding to platelet GPIIb/IIIa receptors. The marketing of this drug provides a new antithrombotic treatment option for patients with acute coronary syndrome who require PCI treatment.

(July 02, 2024)



国家药监局批准枸橼酸倍维巴肽注射液上市

近日，国家药品监督管理局批准百奥泰生物制药股份有限公司申报的1类创新药枸橼酸倍维巴肽注射液（商品名：贝塔宁）上市，该药适用于进行经皮冠状动脉介入术（包括进行冠状动脉内支架置入术）的急性冠脉综合征患者，以降低急性闭塞、支架内血栓、无复流和慢血流发生的风险。

枸橼酸倍维巴肽是一种肽类的血小板GPIIb/IIIa（又称为αIIbβ3）受体拮抗剂，通过阻止纤维蛋白原、Von Willebrand因子和其它粘附配体与血小板GPIIb/IIIa受体结合，抑制血小板的聚集。该药品的上市为需要PCI治疗的急性冠脉综合征患者提供了新的抗栓治疗选择。

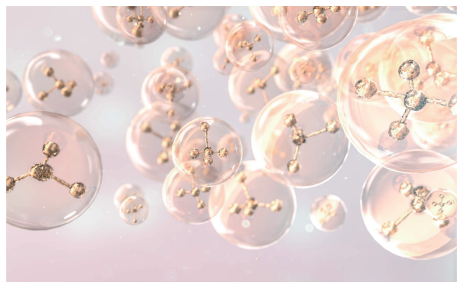
（2024-07-02）

Fultagliptin Benzoate Tablets Approved for Marketing by China NMPA

Recently, the Category 1 innovative drug Fultagliptin Benzoate Tablets (trade name: 信立汀) of Shenzhen Salubris Pharmaceuticals Co., Ltd. is approved by China NMPA. This drug is indicated for improving the blood glucose control for adult patients with type 2 diabetes.

Fultagliptin Benzoate, a dipeptidyl peptidase 4 (DPP-4) inhibitor, can inhibit the activity of DPP-4, and reduce the hydrolysis of incretin hormones by DPP-4, 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 a new treatment option for adult patients with type 2 diabetes.

(July 04, 2024)



国家药监局批准苯甲酸福格列汀片上市

近日，国家药品监督管理局批准深圳信立泰药业股份有限公司1类创新药苯甲酸福格列汀片（商品名：信立汀）上市，该药适用于改善成人2型糖尿病患者的血糖控制。

福格列汀是二肽基肽酶4（DPP-4）抑制剂，可抑制DPP-4活性，减少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，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。

（2024-07-04）

Fulzerasib Tablets Approved with Conditions for Marketing by China NMPA

Recently, the Category 1 innovative drug Fulzerasib Tablets (trade name:达伯特) of Innovent Biologics, Inc. is approved with condition for marketing through the priority review and approval procedure by China NMPA. 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 new treatment options for patients.

(August 21, 2024)

国家药监局附条件批准氟泽雷塞片上

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信达生物科技有限公司申报的1类创新药氟泽雷塞片（商品名：达伯特）上市，该药适用于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。

（2024-08-21）

Medical device

Tendvia™ Pulmonary Artery Thrombectomy System Approved for Marketing

Recently, the innovative product Tendvia™ Pulmonary Artery Thrombectomy System of Shanghai Tendfo Medical Device Co., Ltd. is approved by China NMPA.

The Tendvia™ Pulmonary Artery Thrombectomy System contains two parts: a pulmonary artery thrombectomy device and a thrombus aspiration catheter. The pulmonary artery thrombectomy device is coaxially assembled from a delivery sheath and a push tube with a self-expanding mesh basket structure; the thrombus aspiration catheter consists of an aspiration catheter, a catheter core and an aspirator. This device is indicated to be used for transcatheter thrombectomy in acute high-risk pulmonary embolism or intermediate-risk pulmonary embolism accompanied by clinical deterioration under one of the following circumstances: patients with thrombosis in pulmonary artery trunk or main branch who have a high risk of bleeding or contraindication to thrombolysis; and patients with thrombi in the main pulmonary artery or major branches and who have not responded to thrombolysis or active medical treatment.

This product is the first Pulmonary Artery Thrombectomy System for interventional treatment in China. Taking mechanical thrombolysis, this product reduces the use of thrombolytic drugs and provides a treatment option for patients with contraindications to thrombolysis.

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

(May 31, 2024)

医疗器械

肺动脉取栓支架系统获批上市

近日，国家药品监督管理局经审查，批准了上海腾复医疗科技有限公司生产的“肺动脉取栓支架系统”创新产品注册。

肺动脉取栓支架系统由肺动脉取栓装置和血栓抽吸导管两部分组成。肺动脉取栓装置由输送鞘管和连有自膨式网篮结构的推送管同轴组装而成；血栓抽吸导管由抽吸导管、导管芯和抽吸器组成。用于有下述情况之一的急性高危肺栓塞或伴临床恶化的中危肺栓塞的经导管血栓清除治疗：有肺动脉主干或主要分支血栓，并存在高出血风险或溶栓禁忌的患者；有肺动脉主干或主要分支血栓，并经溶栓或积极的内科治疗无效的患者。

该产品是国内首创介入治疗的肺动脉取栓支架系统。该产品采用机械取栓的方式，减少了溶栓药物的使用，也为具有溶栓禁忌症的患者提供了治疗选择。

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。

（2024-05-31）

Transjugular Intrahepatic Puncture Device Approved for Marketing

Recently, the innovative product “transjugular intrahepatic puncture device” of Beijing Ailin Medical Technology Co., Ltd. is approved for marketing by China NMPA.

The transjugular intrahepatic puncture device contains a stylet needle, a puncture cannula, a guide, an inner guiding tube, an outer sheath tube,a long dilator, and a short dilator. The product is sterilized by ethylene oxide and is intended for single use. It is used for transjugular intrahepatic portosystemic puncture in intrahepatic portosystemic shunt to reduce portal pressure.

This product has pioneered the metal-integrated flexible needle, which is easy to puncture and difficult to deform. The first application of the variable diameter technology has further improved the overall puncture performance of the product and reduced puncture trauma. The first application of the hydrophilic coating technology on transjugular puncture instruments has reduced the pushing resistance and improved the pushing performance of the product. This product can enhance the efficiency of surgery, reduce

经颈静脉肝内穿刺器械获批上市

近日，国家药品监督管理局经审查，批准了北京爱霖医疗科技有限公司生产的“经颈静脉肝内穿刺器械”创新产品注册。

经颈静脉肝内穿刺器械由通芯针、穿刺套管、导向器、导引内管、外鞘管、长扩张器、短扩张器组成。产品经环氧乙烷灭菌，一次性使用。用于经颈静脉肝内门静脉穿刺，进行门静脉的肝内分流手术，以降低门静脉压。

该产品首创金属一体柔性针，易穿刺难变形；变径技术的首次应用，进一步提高产品整体的穿刺性能并减小穿刺创伤；亲水涂层技术在经颈静脉穿刺器械上的首次应用，降低推送阻力、提高产品推送性能。该产品提升手术效率，一定程度上减少并发症，提高安全性。

complications to a certain extent, and improve safety.

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

(May 31, 2024)

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。

（2024-05-31）

Disposable Radiofrequency Atrial Septal Puncture Needle Approved for Marketing

Recently, the innovative product Disposable Radiofrequency Atrial Septal Puncture Needle of Hangzhou Nuosheng Medical Technology Co., Ltd. is approved for marketing by China NMPA.

The Disposable Radiofrequency Atrial Septal Puncture Needle consists of a catheter with a radiofrequency puncture electrode tip and a control handle. It is used in conjunction with the radiofrequency generator and the steerable catheter sheath produced by the same company via the femoral vein approach. It is indicated for patients who are planned to undergo interventional treatment in the department of cardiology through the transseptal puncture route. It helps to perform atrial septal puncture from the right atrium to the left atrium and establish a passage between them, facilitating the smooth entry of subsequent interventional treatment devices into the left atrium.

Compared with traditional mechanical atrial septal puncture products, this product uses radiofrequency energy for puncture, requiring less mechanical force and making the puncture process more controllable. The distal end is made of a flexible and bendable material. When used in combination with other adjustable devices, it can precisely adjust the angle to reach the target tissue and avoid causing damage to non-target tissues. The outlet of the fluid channel is closer to the electrode tip, making the puncture more precise and safer. The handle is equipped with an energy control switch, which has a shorter response time than a foot pedal switch, thus improving the success rate and safety of atrial septal puncture surgeries.

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

(June 12, 2024)

一次性使用射频房间隔穿刺针获批上市

近日，国家药品监督管理局批准了杭州诺生医疗科技有限公司生产的“一次性使用射频房间隔穿刺针”创新产品注册申请。

一次性使用射频房间隔穿刺针由带射频穿刺电极头的导管和控制手柄连接组成，经股静脉入路与该公司生产的射频发生器及可调弯导管鞘配套使用，用于计划接受经房间隔穿刺路径进行心内科介入治疗的患者，通过从右心房行房间隔穿刺至左心房并建立二者之间的通路，辅助后续的介入治疗器械顺利进入左心房。

该产品与传统机械性房间隔穿刺产品相比，采用射频能量穿刺，所需施加机械力更少，穿刺过程更加可控；远端采用可弯曲柔性材质，配合其他可调式器械使用，可精确调整角度到达目标组织，避免对非目标组织造成伤害；流体通道出口更接近电极头，穿刺更精准、安全；手柄具备能量控制开关，较脚踏开关反应时间更短，提升房间隔穿刺手术的成功率和安全性。

药品监督管理部门将加强上述产品上市后监管，保护患者用械安全。

（2024-06-12）

Auxiliary Diagnosis Software for Fundus Images of Fundus Lesions Approved for Marketing

Recently, the Auxiliary Diagnosis Software for Fundus Images of Fundus Lesions of Visionary Intelligence Ltd. is approved for marketing by China NMPA.

The Auxiliary Diagnosis Software for Fundus Images of Fundus Lesions consists of a client side and a server side. The server-side software includes a user registration and login module, a patient information management module, an image automatic analysis module based on deep learning algorithms (including an image quality determination module and a fundus multi-disease recognition module), a report generation and management module, and a system management module.

This product is the first auxiliary diagnosis software for fundus images designed based on multi-disease algorithms. Compared with single-disease algorithms, this product can use a single network model to determine whether there are fundus abnormalities and then identify multiple common fundus diseases.

This product can assist doctors in conducting comprehensive examinations for various fundus diseases. Compared with single-disease auxiliary diagnosis products, it has a broader scope of application, can further enhance the diagnostic capabilities of common fundus diseases in primary medical institutions, encourages a wider range of people to receive early examinations, diagnoses and treatments, reduce the occurrence of visual impairment and blinding diseases, and lower the social burden brought by related diseases.

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

(June 19, 2024)

眼底病变眼底图像辅助诊断软件获批上市

近日，国家药品监督管理局批准了北京致远慧图科技有限公司生产的“眼底病变眼底图像辅助诊断软件”创新产品注册申请。

眼底病变眼底图像辅助诊断软件包含客户端和服务器端，其中服务器端软件包括用户注册与登录模块、患者信息管理模块、基于深度学习算法的图像自动分析模块（包含图像质量判定模块和眼底多病种识别模块）、报告生成和管理模块和系统管理模块。

该产品为首个基于多病种算法设计的眼底图像辅助诊断软件。与单病种算法相比，该产品采用单一网络模型即可判断是否存在眼底异常，进而对多种常见眼底疾病进行识别。

该产品可以辅助医生实施多种眼底疾病综合检查，与单病种辅助诊断产品相比，其适用范围更广，可进一步提升基层医疗机构常见眼底病诊断能力，促使更广泛人群能够接受早期检查和诊疗，减少视力损伤和致盲性疾病的发生，降低相关疾病带来的社会负担。

药品监督管理部门将加强上述产品上市后监管，保护患者用械安全。

（2024-06-19）

Cryoablation Apparatus Approved for Marketing

Recently, the innovative product Cryoablation Apparatus of Shanghai Antaike Medical Technology Co., Ltd. is approved for marketing by China NMPA.

This product consists of a main unit, a gas extension tube and a balloon catheter tail wire. It is used in combination with specific balloon-type cryoablation catheters for the treatment of drug-refractory, recurrent and symptomatic paroxysmal atrial fibrillation in adult patients.

Compared with similar domestic and foreign products that have been marketed in China, the technologies of "adjustable cooling capacity" and "rewarming reminder" used in this product are pioneering. The "adjustable cooling capacity" technology can monitor the freezing temperature in real time and reduce damage to adjacent tissues on the basis of ensuring the effect of cryoablation treatment. The "rewarming reminder" technology can reduce clinical and operational risks such as myocardial damage to patients caused by premature balloon retraction and difficulties in inserting the balloon into the sheath.

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

(July 08, 2024)

冷冻消融仪获批上市

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“冷冻消融仪”创新产品注册申请。

该产品由主机、气体延长管和球囊导管尾线组成，与特定球囊型冷冻消融导管联合使用，用于成人患者药物难治性、复发性、症状性的阵发性房颤治疗。

相较于在我国已上市的国内、外同类产品，该产品使用的“冷量可调”和“复温提醒”技术具有首创性。“冷量可调”技术可实时监测冷冻温度，在保证冷冻消融治疗效果的基础上减少对临近组织的损伤。“复温提醒”技术可以降低提前回缩球囊产生的患者心肌损伤、球囊入鞘困难等临床和操作风险。

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。

（2024-07-08）

FARAWAVE Pulsed Field Ablation Catheter and FARASTAR Pulsed Field Ablation Generator System Approved for Marketing

Recently, the innovative products FARAWAVE Pulsed Field Ablation Catheter and FARASTAR Pulsed Field Ablation Generator System of Farapulse, Inc. is approved for marketing by China NMPA.

The FARAWAVE Pulsed Field Ablation Catheter consists of a Pulsed Field Ablation Catheter and a Catheter Connection Cable. The FARASTAR Pulsed Field Ablation Generator System consists of a pulsed electric field ablator, a recording module, and accessory cables. These two products are used in combination for the treatment of drug-refractory, recurrent and symptomatic paroxysmal atrial fibrillation in patients.

The product utilizes the principle of the non-thermal effect of the pulsed electric field to treat atrial fibrillation. It can achieve the selective destruction of myocardial tissue and avoid the risk of damage to surrounding tissues caused by heat transfer.

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

(July 08, 2024)

一次性使用心脏脉冲电场消融导管和心脏脉冲电场消融系统获批上市

近日，国家药品监督管理局批准了法拉普尔赛股份有限公司（FARAPULSE,Inc.）“一次性使用心脏脉冲电场消融导管”和“心脏脉冲电场消融系统”两个创新产品注册申请。

一次性使用心脏脉冲电场消融导管由心脏脉冲电场消融导管和导管连接电缆组成，心脏脉冲电场消融系统由脉冲电场消融仪、记录模块及附件电缆组成。上述两个产品配合使用，用于患者药物难治性、复发性、症状性的阵发性房颤治疗。

该产品利用脉冲电场的非热效应原理进行房颤治疗，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。

（2024-07-08）

China's Medical Device Standards Reach 1978 in Total

In recent years, the standardization work of medical devices in China has thoroughly implemented General Secretary Xi Jinping's "four strictest requirements", earnestly implemented the National Standardization Development Outline and the 14th Five-Year Plan for National Drug Safety and High-Quality Development, and accelerated the construction of a medical device standard system oriented towards new quality productivity, laying a solid foundation for supporting scientific supervision, facilitating high-tech innovation, promoting high-level opening up, and leading high-quality development.

Adhering to the overall planning of both high-quality development and high-level safety, the standard system has been continuously optimized. The action plan for improving medical device standards has been continuously implemented, the working mechanism has been innovated, the management system has been improved, the optimization and evaluation of

我国医疗器械标准已达1978项

近年来，我国医疗器械标准化工作深入贯彻习近平总书记“四个最严”要求，认真落实《国家标准化发展纲要》《“十四五”国家药品安全及促进高质量发展规划》，加快构建面向新质生产力的医疗器械标准体系，为支撑科学监管、助力高技术创新、促进高水平开放、引领高质量发展奠定了坚实的基础。

坚持统筹高质量发展和高水平安全，标准体系持续优化。持续实施医疗器械标准提高行动计划，创新工作机制，健全管理制度，全面

mandatory standards and the centralized review of recommended standards have been fully completed, a high-quality standard supply system has been constructed, with a focus on supporting the research and development of standards in high-end and innovative fields such as artificial intelligence medical devices and new biomedical materials, and efforts have been made to fill the gaps in standards in innovative fields. Up to now, the number of medical device standards has reached 1978, including 272 national standards and 1706 industry standards; 269 mandatory standards and 1709 recommended standards, basically covering all professional and technical fields of medical devices.

Adhering to the overall planning for the simultaneous improvement of both quantity and quality, the organizational structure of standards has been continuously improved. With scientific planning and rational layout, active efforts have been made to establish medical device standardization technical organizations for national strategic deployment and innovative fields. Standardization organizations for medical robots, artificial intelligence medical devices, medical equipment industry and application, and traditional Chinese medicine instruments have been established successively. There are now 39 medical device standardization organizations in total, basically forming a standard organization system with horizontal to the edge, vertical to the end, and vertical support.

Adhering to the mutual promotion of domestic and international standards, China's international discourse power on standards has been steadily enhanced. Attention has been paid to establishing a scientific, reasonable and highly efficient international standard transformation mechanism. The consistency degree between China's medical device standards and international standards has reached 95%. Since 2023, two international standards led by China have been successfully released, and the work of formulating and revising five international standards has been progressing in an orderly manner. International standards such as the Artificial intelligence medical device—Computer assisted analysis software for pulmonary images—Algorithm performance test methods have been successfully established. Two Chinese experts have been recommended and elected as the chairman of IEC SC 62B and the vice chairman of TC62 respectively, further enhancing the international influence of China's medical device standards.

In the next step, the NMPA will continue to optimize the medical device standard system, improve the efficiency of standard management, deepen international exchanges and cooperation on standards, accelerate the construction of a medical device standard system oriented towards new quality productivity and promote high-quality development, give full play to the guiding, leading and fundamental roles of standards, and provide strong standard technical support for the high-quality development of medical device supervision and industrial innovation.

(July 09, 2024)

完成强制性标准优化评估和推荐性标准集中复审，构建高质量的标准供给体系，重点支持人工智能医疗器械、新型生物医用材料等高端、创新领域标准研制，着力填补创新领域标准空白。截至目前，医疗器械标准已达1978项，其中国家标准272项、行业标准1706项；强制性标准269项、推荐性标准1709项，基本覆盖了医疗器械各专业技术领域。

坚持统筹数量质量双提升，标准组织架构不断健全。科学规划、合理布局，积极组建国家战略部署、创新领域等医疗器械标准化技术组织。医用机器人、人工智能医疗器械、医疗装备产业与应用、中医器械等标准化组织先后成立，医疗器械标准化组织已达39个，基本构建了横向到边、纵向到底、垂直支撑的标准组织体系。

坚持统筹国内国际相互促进，标准国际话语权稳步提升。注重建立科学合理、高效协同的国际标准转化机制，我国医疗器械标准与国际标准一致性程度已达95%。2023年以来，我国主导制定的2项国际标准顺利发布，5项国际标准制修订工作有序推进。《人工智能医疗器械肺部影像辅助分析软件算法性能测试方法》等国际标准成功立项。推荐2名中国专家当选IEC SC 62B主席和TC62副主席，我国医疗器械标准国际影响力进一步提升。

下一步，国家药监局将持续优化医疗器械标准体系，提升标准管理效能，深化标准国际交流与合作，加快构建面向新质生产力、推动高质量发展的医疗器械标准体系，充分发挥标准的导向性、引领性、基础性作用，为医疗器械监管和产业创新高质量发展提供强有力的标准技术支撑。

(2024-07-09)

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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