国家食品药品监督管理总局 CFDA
China Food and Drug Administration

关于《医疗器械优先审批程序》的说明
Explanation for the Priority Approval Procedure of Medical Devices

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一、制定程序的背景
1. Background of formulating the procedure

2014 年 3 月 31 日，国务院发布了新修订的《医疗器械监督管理条例》，其中规定：国家鼓励医疗器械的研究与创新，发挥市场机制的作用，促进医疗器械新技术的推广和应用，推动医疗器械产业的发展。2014 年 2 月 7 日，食品药品监管总局发布了《创新医疗器械特别审批程序（试行）》，对创新医疗器械设置特别审批通道，对鼓励医疗器械创新，促进医疗器械新技术的推广和应用，推动医疗器械产业发展起到了积极作用。

March 31, 2014， the State Council issued the newly revised Regulations for the Supervision and Administration of Medical Devices, and it regulated that the state encourages the research and innovation of medical devices, gives play to the role of market mechanism and promotes the popularization and application for new technology of medical devices in order to promote the development of medical device industry. February 7, 2014, CFDA issued the Special Approval Procedures for Innovative Medical Devices (Trial), which had a positive effect on the setting of special approval channels for innovative medical devices, encouragement of the innovation for medical devices, promotion of the popularization and application for new technology of medical devices and promotion of the development for medical device industry.

为进一步满足人民群众日益增长的使用医疗器械的临床需求，引导和鼓励医疗器械产业创新发展，国家先后出台多项鼓励支持产业发展政策。如《中国制造 2025》（国发〔2015〕28 号）、《国家中长期科学和技术发展规划纲要》（2006-2020 年）、《健康中国 2030 规划纲要》，以及科技部发布的国家科技重大专项或重点研发计划，都将医疗器械创新发展作为推动卫生与健康领域科技创新的重要内容。2015 年，国务院发布了《关于改革药品医疗器械审评审批制度的意见》（国发[2015]44 号），2016 年国务院办公厅发布了《深化医药卫生体制改革 2016 年重点工作任务的通知》（国办发〔2016〕26 号），进一步明确鼓励医疗器械研究和创制，对临床急需医疗器械、儿童、老年人等特殊人群以及罕见病用医疗器械设置审评审批专门通道。

The state has introduced a number of policies to encourage and support the development of industry in order to meet the increasing clinical needs of the people for the use of medical devices, guide and encourage innovation and development of medical device industry. Innovation and development of medical devices are served as an important part of promoting the technical innovation in health fields in the Made in China 2025 (State Council [2015] No.28), Outline of the National Program for Long-and Medium-Term Scientific and Technological Development (2006-2020), Health China 2030 Program and major national R&D projects or key R&D program issued by Ministry of Science and Technology. The State Council issued the Opinions on the Reform of the Review and Approval System of the Drug and Medical Device (State Council [2015] No.44) in 2015, and the General Office issued the Notice on 2016 Key Tasks for Deepening the Reform of the Medical and Health System (State Council [2016] No.26) in 2016 in order to further specify the encouragement of the research and production for medical devices and set up special review and approval channels for the medical devices in clinically urgent need, the medical devices for children, the elderly and other special populations as well as medical devices for rare diseases.

为进一步深化医疗器械审评审批改革，保障医疗器械临床使用需求，在目前已实施的《创新医疗器械特别审批程序》和应对突发公共卫生事件的《医疗器械应急审批程序》的基础上，有必要对治疗罕见病、恶性肿瘤、老年病、儿童专用、临床急需以及列入国家科技重大专项或重点研发计划等情形的医疗器械，制定医疗器械优先审批程序，设置优先审批通道。

In order to further deepen the reform of review and approval for medical devices and ensure the demands of clinical use for medical devices, it's necessary to formulate the priority approval procedure and set up priority approval channels for medical devices used for the treatment of rare diseases, malignant tumors, senile diseases, the medical device specially designed for children, the medical device in urgent needs clinically and the one included in major national R&D projects or key R&D program, etc. based on the Special Approval Procedures for Innovative Medical Devices implemented currently and the

Emergency Approval Procedures for Medical Devices for dealing with public health emergencies.

二、程序的主要内容
2. Main contents of the procedure

2016 年 10 月 25 日，国家食品药品监督管理总局发布《医疗器械优先审批程序》，将于 2017 年 1 月 1 日起施行。
October 25, 2016, China Food and Drug Administration issued the Priority Approval Procedure of Medical Devices and it shall come into force on January 1st, 2017.

本程序共 17 条，包括目的和依据、优先审批的范围、申请、审核、公示程序、优先办理要求、实施日期等内容。
The procedure contains 17 items, including purpose and basis, scope of priority approval, application, review, publicity procedures, requirements for priority handling and implementation date, etc..

（一）优先审批的范围
(1) Scope of priority approval

实施优先审批的医疗器械范围为：一是诊断或治疗罕见病、恶性肿瘤且具有明显临床优势的医疗器械、诊断或治疗老年人特有和多发疾病且目前尚无有效诊断或治疗手段的医疗器械、专用于儿童且具有明显临床优势的医疗器械、临床急需且在我国尚无同品种产品获准注册的医疗器械。二是列入国家科技重大专项或国家重点研发计划的医疗器械。
Scope of medical devices for priority approval: (1) the medical devices for the diagnosis or treatment of rare diseases, malignant tumors and possessing obvious clinical advantages; the medical devices for the diagnosis or treatment of elderly people with specific and multiple diseases lacking effective diagnosis or treatment methods currently; the medical devices dedicated to children and possessing obvious clinical advantages; the medical devices in clinically urgent need and furthermore none of the same type of registered products available in China. (2) The medical devices included in major national R&D projects or key R&D program.

由于可能会有其他情形医疗器械需要优先审批，本程序设置了“其他应当优先审批的医疗器械。”对于其他应当优先审批的医疗器械，食品药品监管总局根据各方面情况和意见，组织专家审查后确定是否予以优先审批。
Because the medical devices in other cases need priority approval, the procedure sets up "other medical devices which shall take priority for approval". For other medical devices which shall take priority for approval, CFDA will determine whether to give priority to its approval after organizing the expert review according to the comprehensive considerations and opinions.

（二）优先审批程序
(2) Priority approval procedures

对注册申请人提出的优先审批申请，属于列入国家科技重大专项或国家重点研发计划的产品，申请人应提交相关证明文件，经总局器审中心审核、公示后，无疑义的实施优先办理。
If the priority approval application proposed by the registration applicant is about the products included in major national R&D projects or key R&D program, the applicant shall submit the related documentary evidence, and the priority handling shall be performed on those products undoubtedly after the review and publicity performed by CFDA Center for Medical Device Evaluation.

对于诊断或治疗特殊疾病或临床急需的产品，以及“其他应当优先审批的医疗器械”，由总局器审中心每个月集中组织专家论证，经公示后，无疑义的实施优先办理。
For the products which are used for diagnosing or treating special diseases or for urgent needs clinically and "other medical devices which shall take priority for approval", the priority handling shall be performed undoubtedly after experts verification and publicity centrally organized by CFDA Center for Medical Device Evaluation each month.

对确定予以优先审批的项目总局器审中心按照接收时间单独排序，优先进行技术审评，省级食品药品监督管理部门优先安排医疗器械注册质量管理体系核查，总局优先进行行政审批。
For the projects which will definitely take priority for approval, CFDA Center for Medical Device Evaluation will sort them separately based on the received time to perform technical review firstly and the provincial food and drug administration will firstly arrange the registration quality management system of medical devices for verification and CFDA will perform administrative approval firstly.

（三）关于罕见病、老年人特有和多发疾病、临床急需等情况的认定