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

总局发布医疗器械优先审批程序
The Priority Approval Procedure for Medical Devices Issued by CFDA

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为进一步落实国务院关于改革药品医疗器械审评审批制度意见，保障医疗器械临床使用需求，国家食品药品监督管理总局经深入研究并广泛征求意见，于近日发布了《医疗器械优先审批程序》，自 2017 年 1 月 1 日起施行。
In order to further implement the Opinions of the State Council Concerning the Reform of the Review and Approval System of the Drug and Medical Device and ensure the demands of clinical use for medical devices, currently, China Food and Drug Administration issued the Priority Approval Procedure for Medical Devices after in-depth study and extensive solicitation of opinions and it will come into force on January 1st, 2017.

根据该程序，食品药品监管总局对下列医疗器械实施优先审批：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。此外，食品药品监管总局将根据各方面情况和意见，组织专家审查后，确定对“其他应当优先审批的医疗器械”予以优先审批。
CFDA performs priority approval for the following medical devices based on the procedure: (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. Furthermore, CFDA will determine whether to give priority to the approval for "other medical devices which shall take priority for approval" after organizing the expert review according to the circumstances and opinions.

对确定予以优先审批的项目，国家食品药品监督管理总局将全环节加快审评审批效率，优先进行技术审评，优先安排医疗器械注册质量管理体系核查，优先进行行政审批，缩短产品上市时间，保证相应成果和产品能够尽快应用于临床使用。
For the projects which definitely take priority for approval, China Food and Drug Administration will speed up the review and approval efficiency in all aspects. They will take priority for technical review, review of the registration quality management system of medical devices and administrative approval to reduce time to market and ensure that the corresponding results and products can be applied to clinical use as soon as possible.

本程序的发布是落实国务院关于转变政府职能，推进“放管服”工作要求的具体体现，将进一步推动我国医疗器械产业发展，促进临床急需等产品尽快进入市场，提升人民群众实现更好的卫生健康水平。
The release of this procedure is a specific embodiment for implementation of the State Council on the transformation of government functions and promotion of the requirements for "Release, Management and Observe" and it will further boost the development of medical device industry in China, promote the products in clinically urgent need to enter the market as soon as possible in order to make people achieve a better health level.

总局关于发布医疗器械优先审批程序的公告（2016 年第 168 号）
Announcement of CFDA on the Release of the Priority Approval Procedure for Medical Devices ([2016] No. 168)

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为保障医疗器械临床使用需求，根据《医疗器械监督管理条例》（国务院令第 650 号）、《国务院关于改革药品医疗器械审评审批制度的意见》（国发〔2015〕44 号）等有关规定，国家食品药品监督管理总局组织制定了《医疗器械优先审批程序》，现予发布，自 2017 年 1 月 1 日起施行。

In order to ensure the demands of clinical use for medical devices, China Food and Drug Administration formulates the Priority Approval Procedure for Medical Devices according to the Regulations for the Supervision and Administration of Medical Devices (State Council Decree No. 650), Opinions of the State Council on the Reform of the Review and Approval System of the Drug and Medical Device (State Council [2015] No.44) and other relevant provisions, which is hereby promulgated and it will come into force on January 1st, 2017.

特此公告。

It is hereby notified.

附件：医疗器械优先审批程序

Annex: The priority approval procedure for medical devices

食品药品监管总局
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