



Explanations on Some Issues Regarding Special Examination and Approval Procedures for Innovative Medical Devices

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China Food and Drug Administration attaches much importance to the innovative development of medical devices. To better implement the *Special Examination and Approval Procedures for Innovative Medical Devices (Trial)* (hereinafter referred to as the Innovative Procedures), concentrate the forces and improve the efficiency for carrying out the special examination and approval of innovative medical devices satisfactorily and encouraging the registration applicants' attention to innovations in research and development, some issues regarding the Innovative Procedures are now explained as follows:

I. When to Apply for Special Examination and Approval of Innovative Medical Devices

Pursuant to the Innovative Procedures, China Food and Drug Administration shall follow the corresponding requirements of the Innovative Procedures to handle any application for special examination and approval of innovative medical devices prior to the application for registration of medical devices.

II. Whether the Innovative Procedures Apply to Class 1 Medical Devices

According to the *Regulation on the Supervision and Administration of Medical Devices* (Decree No. 680 of the State Council), class 1 medical devices are subject to filing administration, but not administrative licensing, so they are not applicable to the Innovative Procedures.

Any application for special examination and approval of any innovative medical device in class 1 medical devices will not be accepted by the China Food and Drug Administration. Where any application for special examination and approval of such innovative medical device has been accepted by the China Food and Drug Administration, if the review proves that the product in the application is classified into class 1 medical devices, it will not be examined or approved in accordance with the Innovative Procedures.

III. Whether Registration Renewal/Change of Licensed Matters Apply to the Innovative Procedures

According to Article 12, Article 14 and Article 17 of the Innovative Procedures, special examination and approval of innovative medical devices is only applicable to the initial registration of medical devices as stipulated in the *Provisions for Registration of Medical Devices* (Order No. 4 of China Food and Drug Administration) and the *Measures for the Administration of Registration of In-Vitro Diagnostic Reagents*

(Order No. 5 of China Food and Drug Administration), and not applicable to registration renewal or change of licensed matters.

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