
**Circular on the Withdrawal Registration Procedures and Subsequent Processing
Methods of Imported Medical Devices that have been Applied for Product Registration
according to Class II and Confirmed as Class III through Technical Review (No. 17 in
2020)**

Recently, during the reviewing processes conducted by our center, it was found that many imported medical devices applied for product registration according to Class II were confirmed as Class III after the technical review, and it was necessary to withdraw from the registration process and reapply for product registration. The procedures for withdrawing from the registration process of the items under review and reapplying for product registration according to the determined management category are announced as follows:

1. The process of withdrawing from the registration procedure for the items under review

If the imported medical device which applies for product registration according to Class II is confirmed as Class III by technical review or its category is confirmed as Class III by the National Medical Products Administration in the supplementary and correction dossiers submitted by applicant, the review conclusion of not being registered will be issued. The reason for not being registered will be indicated in the comprehensive comments and remarks column of the review report as "the applicant applies for product registration according to Class II medical device, but it is confirmed as Class III medical device after technical review". Approval documents for medical device/in vitro diagnostic reagents not to be registered will also state the reasons for not being registered.

If the category confirmation results are submitted in the supplementary and correction dossiers, no other supplementary and correction dossiers are required.

2. Operation mode of reapplying for product registration

After the applicant receives the approval document that the medical device/in vitro diagnostic reagent is not to be registered, it should confirm whether it correctly stated the reason for not being registered; When submitting the registration application again, a copy of approval document on previous medical device/in vitro diagnostic reagent not being registered should be submitted along with the application dossier (CH1.04 Contents). And relevant information

and reasons for the reapplication for product registration shall be explained in the "other issues to be explained" in the application form.

If our center considers it acceptable as it meet the standards of filing and review after review, it will be clearly stated in the filing and review opinions that previous application was filed as an product registration for imported Class II medical devices, and it had withdrawn from the registration process as this product being confirmed as Class III medical device after technical review/category confirmation. Applicant re-file an application for product registration according to the Class III medical device this time and shall make up the difference fee according to the requirements of Article 2 (2) of the *Implementation Rules for the Registration Fee of Medical Devices (Trial)*. And when issuing acceptance opinions, select "Supplement Fee" in "Acceptance Notification Options" to generate a payment notice.

After the applicant pays the difference fee based on the payment notice, and the National Medical Products Administration confirms that the registration fee has been paid, our center shall transfer the item to the technical review process and start the review timing.

The circular is hereby given.

Center for Medical Device Evaluation, NMPA

June 5, 2020

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