Priority Review Program for Medical Devices

I. Purpose:

The purpose of the Priority Review Program for Medical Devices (hereafter "the Program") is to encourage the development of innovative medical devices and medical devices in urgent demand by accelerating the process of obtaining approvals, so as to benefit patients' lives and public health.

II. According to "Regulations Governing Issuance of Medical Device License, Listing and Annual Declaration".

If any of the following circumstances applies to an application, the applicant may submit supporting documents and information to apply for priority review with the central competent authority:

(1) For use in the prevention, diagnosis, or treatment of life-threatening diseases or diseases causing severe disability, with no appropriate medication, medical device, or suitable alternative treatment available yet domestically.

(2) For use in the prevention, diagnosis, or treatment of rare diseases as specified in Paragraph 1 of Article 3 of the Rare Disease and Orphan Drug Act.

(3) Having received priority assistance in accordance with government policies, been subsidized for research and development from the central competent authority or other authority, and conducting or will be conducting clinical trial domestically to verify product safety and efficacy, or meeting the domestic public health or urgent medical needs.

III. Procedure:

A registration may be eligible for the priority review by 2 means:

(1) Submitted with an official letter issued by the competent authority (advanced inquiry required) stating the registration's eligibility for priority review.

(2) Submitted with a "Self-Assessment Form for Priority Review Program for Medical Devices" (attached) and supporting documents to support the statement.

IV. In any of the following circumstances, the competent authority has the right to terminate a priority review, and the registration application under said review shall roll back to a regular review:

(1) The base to obtain the priority review designation no longer stands, due to a change of the applicable laws, regulations, or relevant facts.

(2) The applicant requests for termination.

(3) The materials provided by the applicant are found to be untruthful or misleading.

(4) The competent authority identifies substantial reasons for the continuation of priority review being no longer appropriate.

V. Imposed by competent authority, priority and regular reviews share the same requirements for scientific and clinical evidence, study period and quality of data. For all medical devices must meet the safety, effectiveness, and quality requirements in order to obtain approval from the competent authority.