Thailand FDA - HSA Singapore Regulatory Reliance

Thailand FDA - HSA Singapore Regulatory Reliance is an expedited medical device registration program between regulatory agency that make an offer to the manufacturer or importer to shorten the duration of registration. Since the Medical Device Control Division, Thailand FDA has been recognized the Health Science Authority agency, Singapore as a reference agency, in this program, the Thai FDA will assess the performance and safety of the medical device in cooperate with the Health Science Authority agency, Singapore's evaluation report.

Conditions of participation:

1. A medical device registered in Singapore, and
2. As a risk classification 2-4 or B-D of an In Vitro Diagnostic medical device (IVD) or Non-In Vitro Diagnostic medical device (Non-IVD).

Advantages:

1. The registration costs will be reduced by 53,000 baht (depends on its risk classification), a waiver cost on the expert review process.
2. The average review times for qualifying medical devices will decrease from 150 working days to 60 working days.

Process:

1. Business operators as specified in the establishment license of medical device sign a letter to request a participation in the Regulatory Reliance Program.
2. The manufacturer or importer submits an application for a medical device license through the electronic submission (e-submission) system by attached documents as following:
   (1) The registration documents in the form of Common Submission Dossier Template (CSDT) that is identical to the CSDT documents used to register with the HSA agency,
   (2) The change notification documents that are authorized by the HSA agency (if any),
   (3) The letter to request a participation in the Regulatory Reliance Program,
   (4) The evidence of medical device registration of HSA agency, Singapore.
3. After receiving an application number in the e-submission system, the registrant in Singapore (the company who owns the medical device license from HSA agency) signs the Thailand FDA & Singapore HSA Reliance Model Consent Form (Consent Form) to give a permission for the HSA agency to deliver the evaluation report of medical device to the Medical Device Control Division, Food and Drug Administration, Thailand.
4. **Responsibility of importers in Thailand to Thailand FDA**: Attach the Consent Form in the e-submission system after an officer of Thailand FDA sends the request back to the manufacturer or importer in the e-submission system.
   Responsibility of registrants in Singapore to Singapore HSA: Complete the consent form and include the list of all MEDICS job reference numbers (original new device application and the subsequent change notifications approved in Singapore), and email to hsa_md_info@hsa.gov.sg

The letter to request a participation form

The consent form

For more information:

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Rev.07/01/2022