Timing for Thai FDA Medical Device Registration

Thai FDA amended their timing for Medical Device Registration, by shortening the process in some cases.

After the new Medical Device Act, issued in 2021 (see our article HERE), Thai FDA introduced the concept of Partial registration (partial 1 – partial 2) versus Complete registration. Most of devices can access the Partial 2 procedure.

With the new Medical Device Act timing was slightly increased, now Thai FDA is trying to reduce timing for Medical Device Registration as indicated in below table.

Timing for Thai FDA Medical Device Approval

Medical Device Class	Max Review Time (Working days)
Class 1. Listing Medical Device	
Registration for importation of Listing medical devices not sterile and not for measurements	7
Registration for importation of sterile and measurement Listing medical devices	200
Class 2. Notified Medical Device	
Class 3. Notified Medical Device	
Registration for importation of Notified medical devices in Partial 2 process	150
Registration for importation of Notified medical devices in Full CSDT process	200
Registration for manufacturing or importation of Notified medical devices with Full CSDT with Specialist Review (e.g. innovative Medical Devices)	250
Class 4. Licensed Medical Device	
Registration for importation of Licensed medical devices in Partial 2 process	200
Registration for importation of Licensed medical devices in Full CSDT process	250
Registration for importation of Licensed medical devices in Full CSDT with Specialist Review (e.g. innovative medical devices	300

Timing for Thai FDA Medical Device Registration is calculated from the moment of payment for dossier submission for FDA evaluation. Dossier preparation time is not included.

Is Thai FDA faster than other Regulators?

Compared to other Countries the Time for Medical Device approval in Thailand is shorter: China FDA takes 14-16 months for a class 2; US FDA 510k process is from 9 to 36 months for a class 3.

Medical Device dossier preparation in CSDT or partial 2 is a very sensitive process

Even if your Medical Device has been approved in other ASEAN Country with a CSDT full process, we will need to modify the dossier completely to adapt it to Thai FDA submission requirements. The ASEAN Harmonization gives the guidelines, that Thai FDA follows, but structure of dossier is totally different. We suggest you to consider also a relevant timing for dossier preparation by our staff, based on the information you will provide.

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