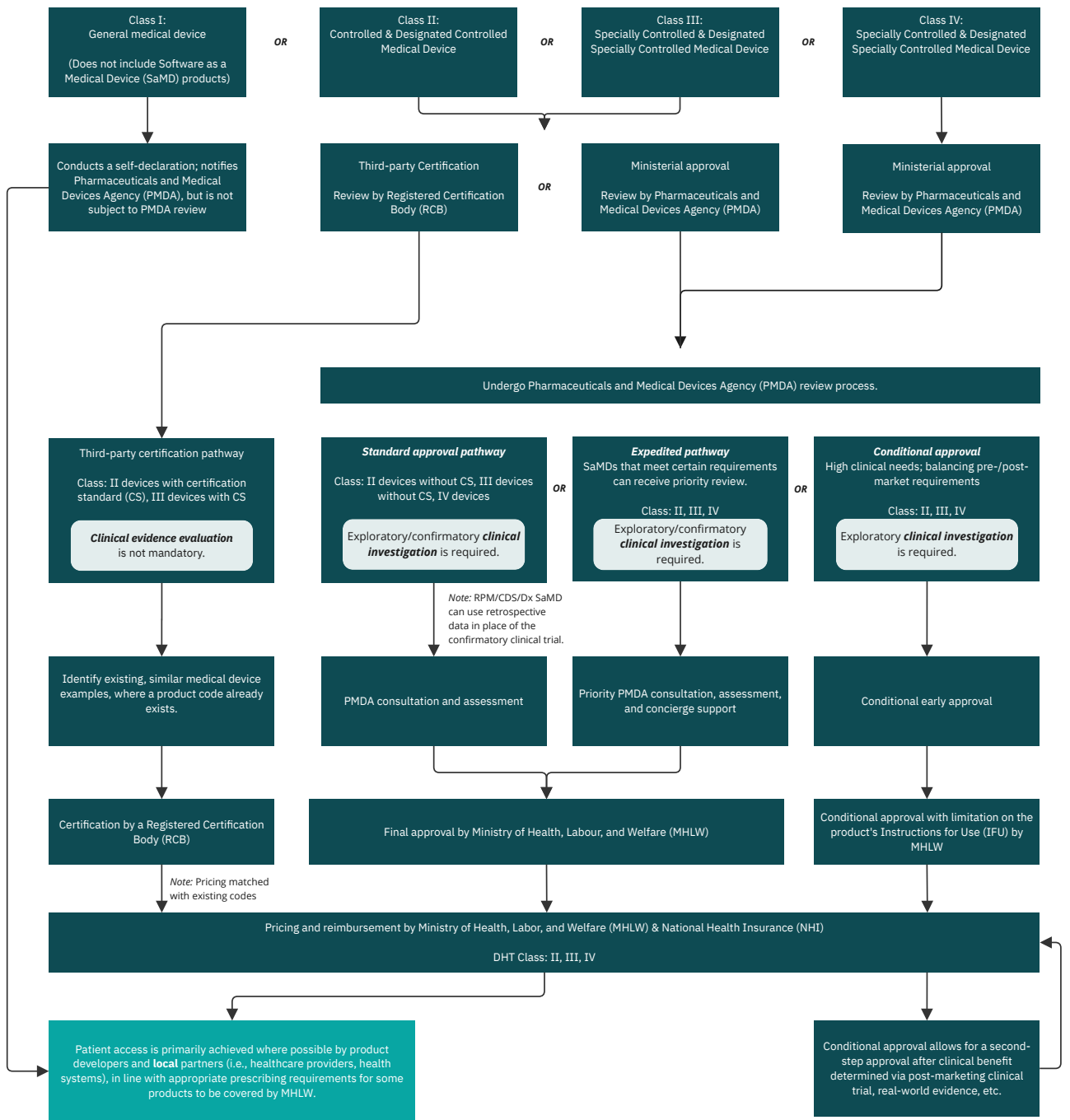


For products that qualify as a medical device, identify the appropriate medical device class and regulatory review pathway.



## Key

Step that applies to a **national** process

Step that applies to a **local** or **regional** level

### Details regarding clinical data:

**Clinical evidence evaluation** refers to the review of published data.

**Clinical investigation** refers to a systematic investigation or study undertaken to verify the safety and performance of a device.