United States Regulatory Process for Medical Devices & IVDs

COSMEREG
US FDA, Health Canada Regulatory Affairs Specialists

Step 1
Classification

Determine the Classification of your device/IVD by searching the FDA Classification Database using relevant search terms, or three letter Product Code and seven digit Regulation number associated with the predicate devices

CLASS I | CLASS II | CLASS III

Step 2
Pre-Sub Meeting

Have a Pre-Submission Meeting with FDA to confirm your medical device/IVD classification and registration pathway to be followed.

Step 3
Demonstrate substantial equivalency to predicate or submit IDE

If your medical device/IVD is Class II, you normally don't need a clinical trial. If it does, follow the IDE route.

If your medical device/IVD is Class III you need to submit an IDE and conduct clinical

Step 4
Regulatory Submission

Demonstrate your medical device/IVD is substantially equivalent to the predicate device(s) and conduct required testing.

Conduct clinical studies and perform testing on your device.

Prepare and Submit 510(k) Premarket Notification. Pay Fee.

Prepare and submit Premarket Approval Application (PMA). Pay Fee.

Step 5
U.S. Agent

If you have no local presence in the U.S., appoint an FDA U.S. Agent as a local point of contact with the FDA.

Step 6
Medical Device/IVD Listing and Facility Registration

List your device and register your company using FURLS system on the FDA website in accordance to 21 CFR Part 807 and pay related fees.

Step 7
Medical device/IVD Sale in US

You can now sell your medical device/IVD in the US.