

Release to Market – FDA Class I Medical Device*

Prepare Notification
for FDA Review
20 to 60 days.

Submission
approved
ready to send
to FDA

FDA Review. Timeline 60 to 150 days.

FDA S/E
Decision.

Distribution of Device

- Device Sponsor has completed design, labeling, safety and effectiveness testing of the device.
- Is a FDA registered device manufacturer.
- Has Quality/GMP procedures in place for this device.

* Certain types of Class I devices are exempted from 510(k) submission requirements.