USFDA 510(K)

DIVYA GANAPATHY

MEDICAL DEVICE REGISTRATION

FDA 510(k) is required for:

- Domestic manufacturers introducing a device to the U.S. market. Re-packers or Re-labellers who **make labelling changes** or whose operations significantly affect the device.
- Anyone who wants to sell a device in the U.S. It is required to make the US FDA 510(k) submission at least 90 days prior to offering the device for sale, even though it may have been under development or clinical investigation before that date.
- Change in the intended use of a device which you already have in commercial distribution.
- If there is a change or modification of a legally marketed device and that change could significantly affect its safety or effectiveness.

MEDICAL DEVICE REGISTRATION

The **medical device manufacturer** which makes the products GMP non exempted are expected to implement the **21 CFR Part 820** as a quality management system.

US FDA 510(k) submission shall be prepared an submitted along with the review fees.

Companies are classified as small business unit based on the company turn over of less than 100 million in an year.

Once the documents submitted, CDRH will review and any queries needs to be addressed

After review, 510(k) number is assigned. The Establishment registration and device listing shall be done in order to supply products in the US.

REGULATORY1 SERVICES

- Regulatory1 helps the clients
  - to register SBU(Small Business Unit), if applicable.
  - Identify the testing requirement of product,
  - creation of the dossier, resolving the queries and after completion of all the activities, the client receives the US FDA 510(k) approval.
  - We assist with the establishment **registration** and device listings to make suitable the supply of medical devices.

Contact us for more information:

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