# FDA PREMARKET NOTIFICATION SUBMISSION 510 (k)

*by Mary Roopsy*


## Premarket Notification-510k

**The class I, II and III medical devices which are intended for the commercial distribution in USA need the FDA clearance**

**FDA clearance is obtained for class I and class II medical devices through Premarket Notification-510k or Premarket Approval PMA**

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**Medical Devices prior to market in the US requires Premarket Notification 510 (k), unless under the requirement of Pre- Market Approval (PMA).**
**It is as per 21 CFR 807 Subpart E of the US FDA regulation.**

# FDA PREMARKET NOTIFICATION SUBMISSION 510 (k)

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**Manufacturer should check the following for the Submission of 510 (k)**

- **Logical Presentation of the data**
- **Test and Data Analysis Scientific Validity**
- **Equivalence demonstration of the subject medical device with the predicate medical device which had been FDA cleared and has been legally marketed in USA.**

# FDA PREMARKET NOTIFICATION SUBMISSION 510 (k)

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**510 (k) shall establish a clear information on below topics**

- **The device description and Intended Use of the device**
- **The test program significant for the particular device and the Intended Use**
- **The Proper and complete Test/ Study Report Summary**

# FDA PREMARKET NOTIFICATION SUBMISSION 510 (k)

*by Mary Roopsy*


**The following information has to be clear before planning for the 510 (k) submission**

- Device classification
- Predicate medical device which is FDA 510 (k) cleared or FDA approved by PMA
- Substantially Equivalence with the predicate medical device
- Selection of type of 510 (k) submission
- Pre submission of 510 (k )

# FDA PREMARKET NOTIFICATION SUBMISSION 510 (k)

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## 510 (k) concerns

- Medical Device classified depending on the class of Risks to class I, II and III
- Three letter Product Codes are given by the FDA for the group of medical devices which can be found from the FDA database.
- 513 (g) program is applicable for not able to classily the medical device

# FDA PREMARKET NOTIFICATION SUBMISSION 510 (k)

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## Predicate Medical Device

**For premarket Notification 510 (k) the medical devices should have a predicate which is already FDA 'cleared ' or FDA 'approved' through PMA, legally marketed in USA ,which is substantially equivalent to the subject device.**

# FDA PREMARKET NOTIFICATION SUBMISSION 510 (k)

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**510 (k) is**

**not a from**

**not a establishment Registration**

**not a device listing not a Premarket Approval.**

**510 (k) is FDA ‘clearance’ for a medical device to legally market in the USA.**

# FDA PREMARKET NOTIFICATION SUBMISSION 510 (k)

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## Substantial Equivalence

Medical device is compared to predicate device to demonstrate either

they have same intended use and same technological characteristics

or

they have same intended use and different technological characteristics with no question on the safety and efficacy.

# FDA PREMARKET NOTIFICATION SUBMISSION 510 (k)

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## 510 (k) typically required for following reasons

- For introducing a new medical device to the US market for the first time.
- Changing the intended use of a previously cleared device
- Making significant changes to the medical device which is already FDA cleared.

# FDA PREMARKET NOTIFICATION SUBMISSION 510 (k)

*by Mary Roopsy*


## Types of 510 (k) Submissions

**-Traditional 510 (k) -** New devices , modifications that require complete review of the test reports, changes in the indications for use

**-Abbreviated 510 (k) -** Device specific FDA guidance available

**-Special 510 (k) -** Modifications that does not require complete review of the test reports

**The Sponsor can perform a Pre-Submission of 510 (k) to get the feedback review by FDA on the main documents such as Intended Use, Predicate Device, Test Protocols etc.**

# FDA PREMARKET NOTIFICATION SUBMISSION 510 (k)

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## Traditional 510 (k) Submission

- It is described in 21 CFR 807.87
- It can be used at any circumstances
- It demonstrates the substantial equivalence with the Predicate medical device.

# FDA PREMARKET NOTIFICATION SUBMISSION 510 (k)

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## Abbreviated 510 (k) Submission

- It is applicable if any specific guidance, special controls, and recognized standards available from FDA.
- It is required under certain circumstances
- Test data may not be required but the test protocols and substantial equivalence with the predicate medical device is discussed

# FDA PREMARKET NOTIFICATION SUBMISSION 510 (k)

*by Mary Roopsy*


## Special 510 (k) Submission

**It is applicable if a device is modified which is previously marketed legally**

**This modification does not affect the intended use or the scientific technology**

# FDA PREMARKET NOTIFICATION SUBMISSION 510 (k)

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## Content of 510 (k)

- Intended use and Indications for Use statement
- Intended use gives the description of general purpose of the device or its function and
- Description that supports the indications for use
- They should be consistent in all the document such as proposed labeling, indications for use etc.
- Format is FDA form 3881

# FDA PREMARKET NOTIFICATION SUBMISSION 510 (k)

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## 510 (k) Summary

It is publically visible document

It is described in 21 CFR 807.92 (a)

It is the basis for a determination of SE.

# FDA PREMARKET NOTIFICATION SUBMISSION 510 (k)

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## DOC or FDA recognized Consensus Standards

**It is a Voluntary program. It is FDA form 3654 which will document the extent of the consensus to the standards. FDA recognized Standards database consists of the standards of AAMI / ANSI / ISO.**

# FDA PREMARKET NOTIFICATION SUBMISSION 510 (k)

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## 510 (k) Submission contain the Device Description

- It is Important and describes the device which includes the device design, diagrams, dimensions , biological and functional characteristics etc
- Patient Contacting Materials
- Energy Sources
- Any other Key technological features

# FDA PREMARKET NOTIFICATION SUBMISSION 510 (k)

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## Substantial Equivalence Discussion

- It is the foundation and important in the 510 (k)
- It is a comparative study of the subject device with the predicate device
- There may be multiple predicates for the comparison
- There may be split predicates for comparison of different characteristics.
- Reference devices may also used to support scientific methodology

# FDA PREMARKET NOTIFICATION SUBMISSION 510 (k)

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## 510 (k) Submission includes Labelling

* This section includes proposed final draft labels, labeling, package inserts, service manuals, IFU, advertising and for promotional materials, Specific intended use, warnings
* Final draft labels are submitted.

# FDA PREMARKET NOTIFICATION SUBMISSION 510 (k)

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## Performance Testing- Bench, Animal or Clinical

**Depending on the technological characteristics different medical devices have different performance testing**

**It include test methods, acceptance criteria and test results for review.**

# FDA PREMARKET NOTIFICATION SUBMISSION 510 (k)

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## Performance Testing- Clinical

**Depending on the technological characteristics different medical devices have different performance testing. It includes the test methods, acceptance criteria and test results for the review**

# FDA PREMARKET NOTIFICATION SUBMISSION 510 (k)

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## 510 (k) Submission should also include

- Table of contents
- Proper Page numbers
- Tables and graphs
- Visual aids, if possible
- Data to be Consistent throughout Submission
- Current applicable FDA guidance documents to be followed.

# FDA PREMARKET NOTIFICATION SUBMISSION 510 (k)

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## Pre Submission for a 510 (k)

- Get FDA review feedback on the medical device 510 (k) submission
- Meetings or teleconferencing depending on the complexity and the requirement of the subject
- E-copy submission

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## Mode of Submission and Feedback

- Two copies of 510 (k)
- One should be electronic copy
- Email to appropriate address
- Method of feedback can be selected as email, meeting or teleconference etc

# FDA PREMARKET NOTIFICATION SUBMISSION 510 (k)

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## 510 (k) Submission Time line

**After 510 (k) submitted FDA checks for the user fee paid and valid E copy. If this step is ok then the Refuse to Accept policy applied which will give result by 15 days. If accepted, Substantiative Interaction Review starts and ends by day 60 and after interactive working with the submitter to resolve the remaining issues Final Decision is received by day 90.**

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