**Contents of a 510(k) Premarket Notification**

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| **What to Include in a 510(k) Premarket Notification** |

1. Format and information required in 510(k) premarket notification are in:
   1. **21 CFR 807.87**
      1. This section outlines the specific information required in a 510(k) submission. This includes details like the device name, classification, description, intended use, labeling, and information on how the device compares to an already approved device (predicate device)
   2. **21 CFR 807.90**
      1. This section focuses on the format of the 510(k) submission. It specifies where to submit the notification and the format for various elements like the cover sheet and technical information.
   3. **21 CFR 807.92**
      1. This section details the content and format of a 510(k) summary. This summary provides a concise overview of the 510(k) submission, explaining how the new device is substantially equivalent to a previously approved predicate device.
   4. **21 CFR 807.93**
      1. This section defines the content and format of a **510(k) statement**. This is a simpler option compared to the 510(k) summary and can be used for specific types of low-risk devices. It focuses on establishing substantial equivalence without the same level of detail as the summary.
2. Contents includes
   1. Device Name
   2. Identification
   3. Registration Number
   4. Classification
   5. Description
   6. Substantial Equivalence Comparison
   7. Software
   8. Standards
   9. Performance
   10. Biocompatibility
   11. Sterility
   12. Shelf Life
   13. Labeling
   14. Class III Certification and Summary
   15. 510(k) Summary of Statement
   16. Truthful and Accuracy Statement
3. Acceptance Checklists for 510(k)s
   1. Traditional
   2. Abbreviated
   3. Special

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| **Start to Finish: 510(k) Premarket Process** |

**Goal:** *The objective of the 510(k) process is to prove substantial equivalence. This means that the manufacture needs to show evidence to the FDA that the medical device intended to bring to the market is broadly similar to another device that is already legally approved on the market a.k.a the predicate device.*

1. **Determine Device Classification**
   1. Class I, II, or III
      1. Class I
         1. Devices are low risk and generally exempt from the 510(k) process. They are subject to general controls i.e:
            1. Establishment registration and device listing
            2. Premarket notification (510(k)) or premarket approval (PMA)

Not applicable to Class I

* + - * 1. Quality system regulations (QSR)
        2. Labeling requirements
        3. Medical device reporting (MDR)
        4. Corrections and removals of devices initiated to reduce a risk to health posed by the device
      1. Class I devices are considered low-risk devices that are not intended for supporting or sustaining life or preventing impairment of human health
      2. Class I Reserved Devices
         1. Device that is intended for a use that is of substantial importance in preventing the impairment of human health or that presents a potentially unreasonable risk of injury or illness
         2. Examples: Blood bank supplies, keratomes, cannulas, cardiovascular surgical; instruments, and positron cameras
    1. Class II
       1. Devices are moderate Risk. They typically go through the 510(k) process
       2. General controls are not sufficient enough to ensure safety and effectiveness
       3. Subject to general controls and special controls
          1. Performance standards
          2. Post market surveillance
          3. Patient registries
          4. FDA Guidelines
    2. Class III – Devices are high risk and usually require a premarket approval (PMA) application

1. **Identify Predicate Device**
   1. Research and Selection
      1. Is a crucial step in the 510(k) process, as it forms the basis for demonstrating substantial equivalence of the new device to an existing, legally marketed device.
      2. The manufacturer conducts research to identify potential predicate devices that are already legally marketed in the United States. This research may involve reviewing FDA databases, such as the 510(k) database, product catalogs, scientific literature, and other relevant sources.
   2. Predicate Criteria
      1. Device Classification
         1. The predicate device must be of the same regulatory class (Class I, II, or III) as the new device or, in some cases, of a lower class
      2. Should have
         1. The same intended use as your device
         2. Similar technology to that involved in the function and operations of your device
         3. The same level of safety and efficacy as your device
2. **Prepare 510(k) Submission**
   1. The manufacture compiles all necessary documentation, including device descriptions, labeling, intended use, performance data, and any clinical studies or data supporting substantial equivalence.
3. **Submit 510(k) to FDA** 
   1. The manufacturer submits the 510(k) application to the FDA. The submission includes a cover letter, a completed FDA Form 3514, and all supporting documentation.
4. **FDA Review**
   1. Upon receiving the submission, the FDA conducts an administrative review to ensure it's complete and contains all necessary information. If deficiencies are found, the FDA may request additional information or clarification from the manufacturer.
5. **Substantive Review**
   1. Once the submission passes the administrative review, the FDA begins the substantive review process. This involves a thorough evaluation of the device's safety and effectiveness compared to the predicate device. The FDA may consult with other experts or advisory panels during this stage.
6. **Decision**
   1. Based on the review, the FDA will make one of the following decisions:
      1. **Substantial Equivalence Determination**: If the FDA determines that the new device is substantially equivalent to the predicate device and meets all regulatory requirements, it issues a clearance letter. The device can then be marketed in the U.S.
      2. **Refusal to Accept (RTA):** If the submission is found to be incomplete or contains major deficiencies, the FDA may issue an RTA letter, indicating that the review process will not begin until the deficiencies are addressed.
      3. **Not Substantially Equivalent (NSE)**: If the FDA determines that the new device is not substantially equivalent to the predicate or raises new questions of safety or effectiveness, it issues an NSE letter. The manufacturer may appeal this decision or submit additional information to address concerns.
7. **Post-Market Requirements**
   1. After clearance, the manufacturer must comply with post-market requirements, including Quality System Regulations (QSR), adverse event reporting, and any specific post-market surveillance studies required by the FDA.
      1. Quality System Regulations (QSR)
         1. Ensure that medical device manufacturers follow good manufacturing practices (GMP) and maintain quality control throughout the manufacturing process.
         2. The QSR is outlined in 21 CFR Part 820.

