Regulatory Overview – 510(k)

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Pediatric Device Workshop

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Overview

- What is a 510(k)?
- What is the 510(k) review process?
- What key factors should be considered for pediatric 510(k) submissions?

510(k)

- The 510(k) process is used to classify individual post-amendment devices:
  - Either find a device substantially equivalent to a predicate; or
  - Find a new device not substantially equivalent that must be placed automatically into class III and require PMA, de novo, or reclassification before marketing in U.S

What is Substantial Equivalence?

1976 Congressional Record

> "The term 'substantially equivalent' is not intended to be so narrow as to refer only to devices that are identical to marketed devices nor so broad as to refer to devices which are intended to be used for the same purposes as marketed products. The committee believes that the term should be construed narrowly where necessary to assure the safety and effectiveness of a device but not narrowly where differences between a new device and a marketed device do not relate to safety and effectiveness."

What is a Predicate?

- 21 CFR Part 807.92(a)(3)*

  An identification of the legally marketed device to which the submitter claims equivalence. A legally marketed device to which a new device may be compared for a determination regarding substantial equivalence is a device that was legally marketed prior to May 28, 1976, or a device which has been reclassified from class III to class II or I (the predicate), or a device which has been found to be substantially equivalent through the 510(k) premarket notification process.

*Regulation written in 1990.

So 510(k) is…

- Premarket Notification
- Section 510(k) of FFD&C Act
- 21 CFR 807 Subpart E
- Determination regarding marketing clearance
- A process that allows FDA to make a determination regarding Substantial Equivalence (SE)
- The classification process for an individual device
- 1986 Guidance on the CDRH Premarket Notification Review Program
  - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081383.htm

A Device Must be Compared to…

- A legally marketed device (a predicate*) that does not require a PMA, i.e.:
  - A pre-amendment device*
  - A device found by FDA to be Substantially Equivalent (SE)
  - A reclassified device*
  - A device classified by a de novo petition

*21 CFR 807.92(a)(3)

A Device is SE if…

- In comparison to a predicate device, it:
  - Has the same intended use, and
  - Has the same technological characteristics as the predicate device,

  or…

A Device is SE if…

- In comparison to a predicate device it:
  - Has the same intended use, and
  - Has different technological characteristics and the information in the 510(k):
    - Does not raise different questions of safety and effectiveness, and
    - Information submitted demonstrates, including appropriate clinical or scientific data, it is at least as safe and effective as the predicate
- Approximately 85% have been determined to be SE

New Technological Features

- Technological differences may include:
  - Modifications in design, materials, or energy sources, for example:
    - changes in the power levels of electrical surgical instruments
    - use of new reagents in in vitro diagnostic devices
    - use of new materials in orthopedic implants
    - use of new battery designs in implanted pacemakers

A Device is NSE if…

- There is no predicate device; or
- It has a new intended use; or
- It has different technological characteristics compared to the predicate device and it raises a different type question of safety and effectiveness; or
- It does not demonstrate that it is at least as safe and effective as the predicate.

Not Substantially Equivalent

- Approximately 3% – 4% have been determined NSE (remaining ~10% are withdrawn or not-a-device).
- Data is looked at last in the 510(k) regulatory process.
- FDA usually asks for additional information at least once prior to determining the device is NSE for lack of data.

Pediatric Considerations

- Indications for use (adult to pediatric or pediatric to adult)
- Are the parameters different
- Biocompability
- Clinical verses other performance data

Data Requirements

- Run a full pre-market pediatric study
- Run a small pre-market pediatric study, borrow from existing adult data
- Run no pediatric study, but indication based on adult data

FDA Tracks for 510(k)s

- The indicated population
- Pediatric - <= 21 means all (neonate, infant, child, adolescent and transitional adolescent)
- If only some of the pediatric age groups are applicable those should be selected

FDA Tracks for 510(k)s

- Category A – adolescent have different consideration than adults
- Category B – adolescents have the same considerations as adults

Important Links

- Device Advice - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm
- CDRH Guidance Document search http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm
- A-Z index: http://www.fda.gov/SiteIndex/default.htm

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Thank You

Questions?