Investigational Device Overview

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What is a Medical Device?

- The term ‘‘device’’ means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is - recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

- intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Examples of Medical Devices

- CT scanners
- ECGs
- Wheelchairs
- Laparoscopes
- Robots
- Virtual reality systems
- Pacemakers
- Electric toothbrushes
- Catheters
- Stents
- In vitro diagnostic kits
- Sutures

When is a Medical Device an Investigational Device?

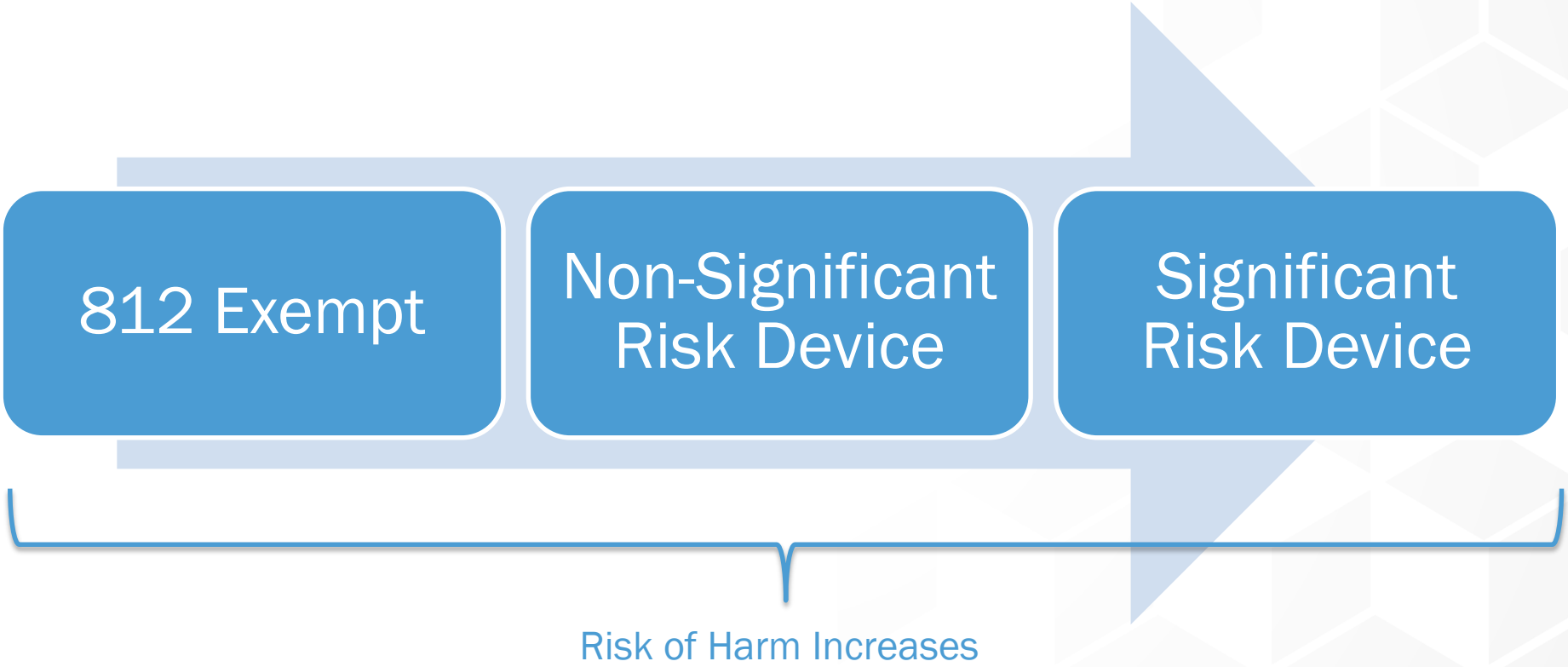
- Activity evaluates the safety or effectiveness of a device in one or more persons
- Data regarding participants or controls will be submitted to or held for inspection by FDA as part of application for a research or marketing permit
- Data regarding use of a device on human specimens will be submitted or held for inspection by FDA as part of application for research or marketing permit.

When is a Medical Device NOT an Investigational Device?

- None of the three previous criteria are met
- The device is not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease. I.e. does not meet the definition of a "medical" device.
- The device is being used as a “tool” to address a research question, collect information or test a physiologic principle. No data is collected about the device itself. I.e. in the research study the (medical) device is NOT investigational. **Not subject to FDA/IDE regulations.**

Types of Investigational Devices and Determinations

Classification of Devices



What should the determination be?

A study is determining the safety and effectiveness of dissolvable sutures

What should the IRB consider for a determination?

SR (Significant Risk Device)

Under 21 CFR 812.3, if one of the following is true for the investigational device:

- Intended use as an implant or for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;

- Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or

- Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject

NSR (Non-Significant Risk Device)

Under 21 CFR 812.3, an NSR device study is one that does not meet the definition for an SR device study.

* Reminder- An NSR determination does not meet minimal risk and should not be confused with expedited/minimal risk.

What should the determination be?

A study is determining the safety and effectiveness of a Urethral Occlusion Device for less than 14 days.

What should the IRB consider for a determination?

812 Exempt

1. Device other than transitional device in commercial distribution before 5/28/1976.

2. Devices introduced after 5/28/1976 that the FDA has determined to be substantially equivalent to devices in #1

3. A device undergoing consumer preference testing, testing of a modification or testing of two or more devices in commercial distribution if not for the purpose of determining safety or effectiveness.

4. Animal Device

5. Custom device, unless the device is being used to determine safety or effectiveness for commercial distribution.

812 Exempt Continued

6. Diagnostic Device Testing Exemption-All Criteria Must be met:
    a) Is noninvasive,
    b) Does not require an invasive sampling procedures that presents significant risk
    c) Does not by design/intention introduce energy into a subject
    d) Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established product or procedure.

510k Clearance

A 510(k) is a pre-market submission made to the FDA for the purpose of demonstrating to the FDA that the device to be marketed is at least as safe and effective, (that is, substantially equivalent) to a legally marketed device.

- If a 510(k) submission is pending the device is still considered investigational
- If 510(k) cleared but a new use is being studied, IDE regulations will apply and a device determination would still be required.
- If the 510(k) approved use of a device is being studied, an 812 exemption can be given.

IRB's Role and Considerations

What is the IRB's Role?

The IRB is designated by the FDA to make the device determination, regardless of the sponsor's or the Principal Investigator's determination.

If the IRB is unsure of the device determination, the FDA can provide consultation and a final determination.

What does the IRB need to consider?

If FDA hasn't already made the risk determination, then it's up to the IRB to decide whether it concurs with the sponsor's or PI's risk assessment. The IRB may disagree with the sponsor's or PI's assessment. Here are some key items the IRB will consider:

- The basis for the risk determination
- The type of harm that may result from use of the device
- Any additional procedures a study subject may need to undergo as part of the study (the IRB must assess the potential harm of the procedure as well as of the device itself)

What does the IRB need to do?

1. Make a device determination for each device in the study.
    a) Document in the minutes the determination for each device
    b) Include any relevant discussion regarding risk and the boards analysis

If SR Device

1. Notify sponsor and investigator of SR decision.
2. The IRB can approve the study as greater than minimal risk with the condition that the study may not commence until an IDE has been provided by the FDA.
3. After IDE obtained by sponsor, the IDE can be submitted to the IRB and human subject research can begin after final approval.

If NSR Device

1. Proceed to review study as normal, as greater than minimal risk study (Full Board), as an IDE is not required

If 812 Exempt Device

1. Proceed to review study as normal, may consider minimal risk (Expedited Cat 1.) depending upon remaining research activities.

When should an electronic application be considered an investigational device?

When the app meets the definition of investigational device.

The FDA does not plant to enforce for the following:

1. Help patients self-manage their disease or condition without providing specific treatment or treatment suggestions;
2. Provides patients with simple tools to track health information;
3. Provides patients with easy access to information related to patient's health information;
4. Help patients document, show or communicate to health care providers
5. Automate simple tasks for health care providers
6. Enable patients to interct with PHI or EHR systems; or
7. Intended to transfer, store, convert format, and display device data in its original format from a medical device.

What should the determination be?

A study is determining the safety and effectiveness of an insulin pump that utilizes an application to read glucose levels and provide insulin dosing to subject.

What should the IRB consider?

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