Addendum 2

Device Definitions

Classification of devices: The class distinction is made primarily on the level of risk to users/patients and therefore, the level of FDA oversight needed to ensure that the device is safe and effective as labeled.

- Class I/General Controls: Many devices need very little regulation to assure that they are safe and effective. Basic controls such as those on manufacturing and claims were expected to be sufficient. Examples: Crutches, band-aids, cast components, etc.
- Class II/Special Controls:
  This is the largest device category and encompasses those device types that could be considered to be safe and effective if they met Class I restrictions and if there were some additional standards according to the kind of device. Examples: wheelchairs, tampons, magnetic resonance imager, etc.
- Class III/Premarket Approval: These are devices about which there is insufficient information to determine that they are safe and effective. Any "new" devices (i.e., they are not substantially equivalent to any prior device) about which there are few or no data are automatically Class III. Examples: heart valves (known to present hazards requiring clinical demonstration of safety and effectiveness) OR not enough known about safety or effectiveness to assign to Class I or II.

Custom Device: A device that:

- Necessarily deviates from devices generally available or from an applicable performance standard or premarket approval requirement in order to comply with the order of an individual physician or dentist;
- Is not generally available to, or generally used by, other physicians or dentists;
- Is not generally available in finished from for purchase or for dispensing upon prescription;
- Is not offered for commercial distribution through labeling or advertising; and
- Is intended for use by an individual patient named in the order of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice.

Implant: A device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more. FDA may, in order to protect public health, determine that devices placed in subjects for shorter periods are also "implants".

Investigation: A clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device.

Investigational Device: A device, including a transitional device that is the object of an investigation.

Investigational Device Exemption (IDE): Allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket

Approval (PMA) application or a Premarket Notification [510 (k)] submission to FDA. Clinical studies are most often conducted to support a PMA. Only a small percentage of 510(k)'s require clinical data to support the application. Investigational use also includes a clinical evaluation of certain modifications or new intended uses of legally marketed devices. All clinical evolutions of investigation devices, unless exempt, must have an approved IDE before the study is initiated. Clinical evaluation of devices that have not been cleared for marketing requires:

- An IDE approved by an institutional review board. If the study involves a significant risk device, the IDE must also be approved by FDA;
- Informed consent from all patients;
- Labeling for investigational use only;
- Monitoring of the study and ;
- Required records and reports.

Medical Device: 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 Pharmacopoeia, 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 (21 U.S.C. 321 (h)).
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Premarket Approval (PMA): Any premarket approval application for a Class III medical device, including all information submitted with or incorporated by reference therein (21 CFR 814.3) PMA is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Due to the level of risk associated with Class III devices, FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of class III devices. Therefore, these devices require a PMA application under section 515 of the FD 7C Act in order to obtain marketing clearance. A PMA application is the most stringent type of device marketing application for medical devices. FDA approves a PMA if it determines that the application contains sufficient valid scientific evidence to provide reasonable assurance that the device is safe and effective for its intended use(s).

Premarket Notification (PMN or 510(k)): 510(k) refers to the premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims. A legally marketed device is a device that was legally marketed prior to May 28, 1976 (preamendments device), or a device which has been reclassified from Class III to Class II or I, a device which has been found to be substantially equivalent to such a device through the 510(k) process, or one established through Evaluation of Automatic Class III Definition. The legally marketed device(s) to which equivalence is drawn is known as the "predicate" device(s).

Noninvasive: When applied to a diagnostic device or procedure, means one that does not by design or intention: (1) Penetrate or pierce the skin or mucous membranes of the body, the ocular cavity, or the urethra, or (2) enter the ear beyond the external auditory canal, the nose beyond the rectum, or the vagina beyond the cervical os. For purposes of this part (812) blood sampling that involve simple venipuncture is considered noninvasive, and the use of surplus samples of body fluids or tissues that are left over from samples taken for noninvestigational purposes is also considered noninvasive.

Non-Significant Risk Device: A device that is not a significant risk device. NSR device studies do not have to have an IDE application approved by FDA.

Significant Risk Device: An investigational device that:

- Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is purported or represented to be for a use in 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.

Substantial Equivalence (SE): A new device is as safe and effective as the predicate device(s). A device is SE if, in comparison to a predicate device it:

- Has the same intended use as the predicate device; and
- Has the same technological characteristics as the predicate device; or
- Has different technological characteristics, that do not raise new questions of safety and effectiveness, and the sponsor demonstrates that the device is as safe and effective as the legally marketed device.

Transitional Device: A device subject to section 520 (1) of the act, that is, a device that FDA considered to be a new drug or an antibiotic drug before May 27, 1976.