Joint Meeting of the Dental Products Panel of the Medical Devices Advisory Committee of the Center for Devices and Radiological Health and the Peripheral and Central Nervous System Drugs Advisory Committee of the Center for Drug Evaluation and Research

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Overview of Device Classification Process

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Medical Device Amendments to Federal Food, Drug, & Cosmetic Act (FF,D,&C Act)

- May 28, 1976
- Defined a device (201(h) of the Act)
- Required classification of device types according to potential risk
- Required premarket review of devices for the first time

Preamendment Devices
vs.
Postamendment Devices

- The FF,D,&C Act divided the arena of medical devices:

Preamendment Devices (Pre - May 28, 1976)

"Grandfathered" if Legally Marketed

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Postamendment Devices (Post - May 28, 1976)

Require Premarket Review Unless Exempt by Regulation

Preamendment Devices

- Preamendment devices (devices on the market prior to May 28, 1976) are "grandfathered" devices for purposes of premarket review:
  - serve as **predicate** devices for postamendment devices;
  - can remain on the market (unless legal action is taken to remove them or unless classified into Class III and FDA has issued a regulation requiring premarket approval applications (PMAs) for them); and
  - include dental mercury, amalgam alloy and encapsulated amalgam.

Postamendment Devices

- Introduced into commercial distribution after May 28, 1976
- Require premarket review
- If a new manufacturer wishes to market the same type device as one that is grandfathered, the manufacturer must submit a premarket notification submission (510(k)), demonstrating "substantial equivalence" (SE), and receive clearance.

Device Regulation is Risk Based

- Section 513(a)(2) of the FF,D,&C Act requires FDA to determine **safety and effectiveness** of a device by weighing any **probable benefit** to health from the use of the device against any **probable risk** of injury or illness from the use.

Classification is Risk Based Under the FF,D,&C Act

- Three Regulatory Classes (level of control, **based on risk**, necessary to provide reasonable assurance of safety and effectiveness of a device type):
  - **Class I** – General Controls
  - **Class II** – General Controls & Special Controls
  - **Class III** – General Controls & Premarket Approval Application (PMA)

Description of Classes

- **Class I -**
  - Devices for which **general controls** are sufficient to provide reasonable assurance of safety and effectiveness.

Description of Classes (cont.)

General controls include:

- Prohibition against misbranding and adulteration;
- Premarket notification (510(k)) requirements;
- Good Manufacturing Practices (GMPs);
- Adverse event reporting; and
- Repair, replacement, refund.

Description of Classes (cont.)

- **Class II -**
  - Devices which cannot be classified into Class I because general controls by themselves are **insufficient** to provide reasonable assurance of safety and effectiveness, **but**
  - For which there is **sufficient information** to establish performance standards or, after 1990, **special controls,** to provide such assurance.

Description of Classes (cont.)

- **Special Controls include:**
  - Performance standards (national or international consensus standards recognized by rulemaking);
  - Voluntary standards;
  - Guidance documents;
  - Postmarket surveillance;
  - Patient registries; and
  - Other actions the agency decides are necessary to provide reasonable assurance of safety and effectiveness.

Description of Classes (cont.)

Class III -

- Devices for which insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of safety and effectiveness; and
- Such devices:
  - Are life sustaining or life supporting;
  - Are of substantial importance in preventing impairment of human health; or
  - Present potential unreasonable risk of illness or injury.

Regulatory Class Determines Type of Premarket Submission

- **Class I** = **exempt** from premarket review **unless 510(k) is required** by regulation
- **Class II** = 510(k) **required unless exempt** from 510(k) requirements by regulation
- **Class III** = PMA required (applicant must demonstrate safety and effectiveness of its device without relying on a grandfathered/predicate device)

What is a 510(k) (Premarket Notification)?

- Section 510(k) from the 1976 Medical Device Amendments to the FF,D,&C Act:
  - Is the most common path to market for medical devices;
  - Is a review to determine whether a device is SE to a device type that was legally on the market prior to May 28, 1976 (grandfathered type device) and for which PMAs have not been required; and
  - Submitter is required to show that a postamendment (new) device is SE to a legally marketed device for which PMA is not required.
  - FDA's determination of SE serves as the **classification** process for individual postamendment devices.

What is Substantial Equivalence?

- A new device is deemed SE to a predicate device if:
  - It has same intended use;
  - It has same technological characteristics; or
  - It has different technological characteristics, but it does not raise different questions of safety and effectiveness; and
  - It is at least as safe and effective as the predicate device.

What is Substantial Equivalence? (cont.)

- Under the 1976 law, a SE determination is a classification that means the new device is in the **same** class, and will be regulated the same way, as the grandfathered/predicate device type.
  - For example, because amalgam alloy is classified in Class II, a new manufacturer's amalgam alloy, that is determined to be SE, would **also** be classified into Class II.

How Did Device Types First Get Classified?

- As required by the 1976 Medical Device Amendment to the FF,D,&C Act, FDA met publicly with our Advisory Panels to receive their recommendations on the classification into class I, II, or III of legally marketed preamendment device types (**grandfathered device types**).

- Recommendations were **risk based** to address safety and effectiveness of each device type.

How Did Device Types First Get Classified? (cont.)

- FDA reviewed the recommendations.
- FDA issued proposed rules classifying each device type, which included the Panel's recommendation and FDA's proposed classification for each device type.

How Did Device Types First Get Classified? (cont.)

- After reviewing the comments, FDA published the final classification regulations, including FDA's responses to the comments received.

- Over 1700 device types have been classified though this process.

Can the Classification of a Preamendment Device Type Be Changed?

- Yes
- Through notice and comment rulemaking
- Based on new information

Can a Device Type be Banned from the Market?

- Yes
- Banning provision in section 516 of the FF,D,&C Act.
- Legal standard:
  - the device type presents **substantial deception** or an **unreasonable and substantial risk** of illness or injury; and
  - labeling or change in labeling **cannot** address deception or risk.

Dental Classification Advisory Panel

- First met 1976-78.
- After the public meetings, and notice and comment rulemaking, FDA classified the following:

–**Dental mercury** – is a device composed of amalgam alloy in the restoration of a dental cavity or a broken tooth.
Class I (**510(k) required**); and

–**Amalgam alloy** – is a device that consists of a metallic substance intended to be mixed with mercury to form filling material for treatment of dental caries.
Class II (**510(k) required**).

Device Types

- **Dental Amalgam** consists of dental mercury and amalgam alloy:
  - mixed together in a dentist's office to form dental amalgam;
  - can be sold separately or together; and
  - when packaged together is called **encapsulated amalgam.**
- Dental amalgam and encapsulated amalgam were not separately classified during the 1976-1978 classification process.

Device Types (cont.)

- FDA has subsequently **classified** dental amalgam and encapsulated amalgam through the 510(k) process. Dental amalgam, including encapsulated amalgam, are both a combination of:
  - dental mercury, a class I type device; and
  - amalgam alloy, a class II type device.
- When a class I and class II device are combined, the device is regulated at the **higher class**, Class II.
- Because they are a combination of a Class I and II device, dental amalgam and encapsulated amalgam are regulated as Class II devices.

510(k) for Dental Amalgam

- Substantial Equivalence - in comparison to a grandfathered/predicate device (e.g., dental mercury and amalgam alloy):
  - It has same intended use;
  - It has same technological characteristics; or
  - It has different technological characteristics, e.g., change in alloy particle size, that do not raise different questions of safety and effectiveness; and
  - Performance data/information, e.g., bench data testing, show it to be at least as safe and effective as the predicates (dental mercury and amalgam alloy).

Premarket Clearance History

- To date FDA has cleared:
  - Seventy-five 510(k) submissions for dental amalgams as Class II devices (most recent in 2005); and
  - Three 510(k) submissions for dental mercury as Class I devices (most recent in 1998).

FDA Proposed Reclassification

- 1990 Safe Medical Devices Act to the FF,D,&C Act gave FDA additional authorities over Class II device types ("special controls").

- 1993-1994 Dental Products Advisory Panel met and recommended **upclassification** for dental mercury from Class I to Class II in order to apply uniform special controls for dental mercury and dental amalgam products.

- 1994-1998: Various international meetings and reports on the risks and benefits of dental amalgams.

- 1997: Public Health Service update of peer reviewed literature on dental amalgams.

FDA Proposed Reclassification (cont.)

- 2002 FDA proposed regulations that would upclassify dental mercury from Class I to Class II and place all of these device types into Class II.

- FDA also proposed a Special Controls Guidance Document that included consensus standards, labeling requirements, and labeling recommendations.

- Final rule has not issued and, therefore, is not in effect.

Status Update

- FDA received more than 700 comments on the proposed reclassification;
- Public comments raised potential safety concerns that the agency wanted to evaluate;
- FDA performed a new literature review (9 years since the last Public Health Service review).
- Draft of the white paper on the literature review will be presented to the Panel at this meeting.

Thank you!