24 Hour Summary
General and Plastic Surgery Devices
Advisory Committee Meeting
October 27, 2022

Introduction:

On October 27, 2022, FDA conducted a Public Advisory Committee meeting to discuss and make recommendations on the classification proposals for nail prostheses, which are currently unclassified preamendments devices, to be class I (general controls); and ultrasonic surgical instruments, single-use reprocessed ultrasonic surgical instruments, and neurosurgical ultrasonic instruments, which are all currently unclassified preamendments devices, to be class II (general and special controls).

Panel Deliberations/FDA Questions:

Session I

The Panel discussed the following FDA-identified risks to health for nail prostheses:

- Adverse tissue reaction
- Discomfort, pain or nail breakage
- Nail infection

The Panel agreed with inclusion of the above FDA-identified risks in the overall risk assessment of nail prostheses under product code "MQZ".

The Panel unanimously agreed with the FDA's proposed classification of class I (general controls) for nail prostheses.

Session II

The Panel discussed the following FDA-identified risks to health for ultrasonic surgical instruments, single-use reprocessed ultrasonic surgical instruments, and neurosurgical ultrasonic instruments:

- Infection
- Adverse tissue reaction
- Bleeding, hemorrhaging, blood loss
- Tissue injury (thermal, mechanical, electrical, software malfunction, use error)
- Interference with other devices

The Panel agreed with inclusion of the above FDA-identified risks in the overall risk assessment of ultrasonic surgical instruments, single-use reprocessed ultrasonic surgical instruments, and neurosurgical ultrasonic instruments under product codes "LFL", "NLQ", and "LBK". The Panel specifically recommended that death and device breakage be incorporated into the device risks.

The Panel discussed the identified special controls and whether they appropriately mitigate the identified risks to health, or if additional or different special controls were necessary. The Panel generally agreed that the identified proposed special controls adequately covered the risks and safety concerns discussed. The Panel also recommended the follow additional mitigating measures:

- Requiring 100% quality inspections for device release rather than sample quality testing to mitigate the risk of device breakages caused by inadequate design or manufacturing process controls.
- Develop validation methods for the maximum number of reprocessing cycles for cleaning and sterilization of reprocessed devices without causing an adverse change in the material integrity and have acceptance criteria that can detect bioburden remaining on the device (e.g., within small channels in the device that may be difficult to clean).
- Improve reprocessing instructions in the labeling based on the cleaning and sterilization validation to ensure proper cleaning and sterilization of the reprocessed devices.
- Specificity of "worst-case" scenarios for performance testing, especially with respect to the device use-life, which should encompass the maximum duration of use of the device for the maximum number of expected surgical procedures and reprocessing cleaning and sterilization cycles. The tested use-life should be included in the labeling.
- Recommended pyrogenicity be evaluated for ultrasonic surgical instruments, single-use reprocessed ultrasonic surgical instruments, and neurosurgical ultrasonic instruments.

The Panel unanimously agreed with the FDA's proposed classification of class II (general and special controls) for ultrasonic surgical instruments, single-use reprocessed ultrasonic surgical instruments, and neurosurgical ultrasonic instruments.

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Transcripts:

Transcripts may be downloaded from:
October 26-27, 2022: General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee Meeting Announcement - 10/26/2022 | FDA

OR

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