Classification of Ultrasonic Surgical Devices
FDA Questions

General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee

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1. FDA has identified the following risks to health for ultrasonic surgical devices:

Identified Risk	**Description/Examples**
Infection	This can result from the use of devices that are not adequately sterilized or reusable device components that are not adequately cleaned and sterilized.
Adverse Tissue Reaction	This can result from the use of device materials that are not biocompatible and may also result from non-resorbable material fragments from the device left in the body due to device mechanical failure.
Bleeding/Hemorrhaging/Blood Loss	This can result from unintended damage to surrounding blood vessels or device malfunction/failure leading to a failure to seal or cauterize.
Tissue Injury (Thermal, Mechanical, Electrical)	Tissue injury can result due to excessive energy or heat applied to tissues causing burns or thermal injury, or mechanical injury due to the power of the device from fragmentation, emulsification, and aspiration. Tissue injury can occur from electric shock resulting from malfunction or failure of the electrical components of the device. Tissue injury can also result in: • Neurological Deterioration (neurological indications) • Prolonged surgical procedure • Death
Interference with other Devices	Device electromagnetic (EM) emissions may affect other nearby surgical equipment. Device may be susceptible to EM interference from emissions from other nearby surgical equipment.

Please comment on whether you agree with inclusion of all the risks in the overall risk assessment of ultrasonic surgical devices under product codes "LFL", "NLQ", and "LBK". In addition, please comment on whether you believe that any additional risks should be included in the overall risk assessment of these ultrasonic surgical devices.

2. Section 513 of the Food, Drug, and Cosmetic Act states a device should be Class III if:

    - insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of its safety and effectiveness, AND

    - if, the device is purported or represented to be for use in supporting or sustaining human life, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.

    A device should be Class II if:

    - general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness, AND

    - there is sufficient information to establish special controls to provide such assurance.

    A device should be Class I if:

    - general controls are sufficient to provide reasonable assurance of the safety and effectiveness, OR
    - insufficient information exists to:
        - determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness, OR
        - establish special controls to provide such assurance, BUT
            I. is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and
            II. does not present a potential unreasonable risk of illness or injury.

    FDA believes general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness and sufficient information exists to establish special controls to adequately mitigate the risks to health and provide reasonable assurance of device safety and effectiveness for this device type. As such, FDA believes that Class II is the appropriate classification for ultrasonic surgical devices. Following is a risk/mitigation table which outlines the identified risks to health for this device type and the recommended controls to mitigate the identified risks.

Risk/mitigation recommendations for ultrasonic surgical devices under product codes LFL, NLQ, and LBK

Identified Risk	Recommended Mitigation Measure
Infection	Sterilization Validation Reprocessing Validation Pyrogenicity Evaluation (neurosurgical devices only) Shelf-life Testing Packaging Validation Labeling
Adverse Tissue Reaction	Biocompatibility Evaluation Shelf-life testing
Bleeding, Hemorrhaging, Blood Loss	Non-clinical Performance Testing Bench Testing Animal Performance Testing
Tissue injury resulting from: Thermal effects, burns Mechanical failure, device breakage Electrical hazards, shock Software malfunction Use error	Labeling Non-clinical Performance Testing Bench Testing Device Reliability Testing Electrical Safety Testing Electromagnetic compatibility (EMC) testing Software Verification, Validation, and Hazard Analysis Animal Testing Shelf-Life Testing Use-Life Testing
Interference with other Devices	Electromagnetic Compatibility (EMC) Testing Labeling

Please discuss whether the identified special controls for ultrasonic surgical devices under product codes LFL, NLQ, and LBK appropriately mitigate the identified risks to health and whether additional or different special controls are recommended:

1. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including the following:
   a. Characterization of the ultrasonic and power parameters (e.g., sonication frequency and displacement, irrigation rate, suction (negative) pressure).
   b. Bench testing of material strength to demonstrate the device will withstand forces encountered during use and maintain device integrity over the labeled shelf-life and use-life, including repeated cleaning/use cycles if reprocessed.

2. Software used to operate the device hardware must be described in detail in the software requirements specification (SRS) and software design specification (SDS). Software verification, validation, and hazard analysis must be performed.

3. Electrical safety, thermal safety, mechanical safety, and electromagnetic compatibility (EMC) testing must be performed.

4. Performance data must demonstrate the sterility of the tissue-contacting components of the device and must evaluate pyrogenicity (if intended for neurosurgical use).

5. Performance data must support the shelf-life and use-life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf-life and use-life.

6. The tissue-contacting components of the device must be demonstrated to be biocompatible.

7. Animal performance data must demonstrate that the device performs as intended and will not result in unintended tissue injury, including mechanical and thermal damage to surrounding tissue structures.

8. The labeling must include:
   a. Qualifications needed for the safe use of the device.
   b. A detailed summary of the device technical parameters.
   c. A detailed summary of the device- and procedure-related complications pertinent to use of the device.
   d. Information on how the device operates.
   e. A shelf-life for sterile components.
   f. The use-life of the device for reusable components.
   g. Validated methods and instructions for reprocessing of any reusable components.
   h. Information on the electrical safety and electromagnetic compatibility of the device.
   i. Prominent labeling adjacent to original equipment manufacturer (OEM) identifying the reprocessor for single-use reprocessed ultrasonic surgical instruments.

3. **Please discuss whether you agree with FDA's proposed classification of Class II with special controls for ultrasonic surgical devices under product codes "LFL," "NLQ," and "LBK". If you do not agree with FDA's proposed classification, please provide your rationale for recommending a different classification.**