Classification of Mammary Sizers
FDA Questions

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

October 26-27, 2022

1. FDA has identified the following risks to health for mammary sizers:

Identified Risk	Description/Examples
Adverse tissue reaction	Device material(s) may elicit adverse tissue reactions, such as allergic reaction, toxicity, and foreign body response.
Infection	Inadequate device sterilization or packaging integrity may lead to infection leading to additional surgical procedures.
Device malfunction leading to increased operative time	Device malfunction may result in rupture, gel bleed, and gel migration leading to increased operative time and additional risks, such as increased anesthesia.
Use error/Improper device use	This can result from the device accidentally remaining implanted and not exchanged for a permanent breast implant.

Please comment on whether you agree with inclusion of all the risks in the overall risk assessment of mammary sizers under product code "MRD". In addition, please comment on whether you believe that any additional risks should be included in the overall risk assessment of these mammary sizers.

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 a 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 mammary sizers. 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 mammary sizers under product code "MRD"

Identified Risk	**Recommended Mitigation Measure**
Adverse tissue reaction	Biocompatibility evaluation Labeling
Infection	Sterilization testing/validation/information Reprocessing validation Shelf-life validation Labeling
Device malfunction leading to increased operative time	Non-clinical performance testing Labeling
Use error/Improper device use	Labeling

Please discuss whether the identified special controls for mammary sizers appropriately mitigate the identified risks to health and whether additional or different special controls are recommended:

1. Non-clinical performance testing must demonstrate the mechanical function and durability of the device.

2. The device must be demonstrated to be biocompatible.

3. Performance data must demonstrate the sterility of the device.

4. Performance data must support the shelf life of the device by demonstrating continued sterility and package integrity over the intended shelf life.

5. Performance data must validate the cleaning and disinfection instructions for reusable devices.

6. Labeling must bear all information required for the safe and effective use of the device, specifically including the following:
   i) A clear description of the technological features of the device, including identification of device materials, shapes, and sizes.
   ii) Information on how the device operates.
   iii) Validated methods and instructions for reprocessing if the device is reusable, including the number of times device can be re-sterilized.
   iv) A warning against implantation of the device.
   v) A shelf life.
   vi) Disposal instructions.

3. **Please discuss whether you agree with FDA's proposed classification of Class II with special controls for mammary sizers. If you do not agree with FDA's proposed classification, please provide your rationale for recommending a different classification.**