

Reclassification of Urogynecologic Surgical Mesh Instrumentation FDA Questions

Gastroenterology and Urology Devices Panel of Medical Devices Advisory Committee
February 26, 2016

1. The FDA has identified the following risks to health of urogynecologic surgical mesh instrumentation based upon FDA's review of literature, information available to FDA regarding the marketed devices, and the Manufacturer and User facility Device Experience (MAUDE) databases:
 - Perioperative risks. Organ perforation or injury and bleeding (including hemorrhage/hematoma).
 - Damage to blood vessels, nerves, connective tissue, and other structures. This may be caused by improperly designed and/or misused surgical mesh instrumentation. Clinical sequelae include pelvic pain and neuromuscular problems.
 - Adverse Tissue Reaction. This may be caused by non-biocompatible materials.
 - Infection. This may be due to inadequate sterilization and/or reprocessing instructions or procedures.
 - a. **Please comment on whether this list completely and accurately identifies the risks to health presented by urogynecologic surgical mesh instrumentation.**
 - b. **Please comment on whether you disagree with inclusion of any of these risks, or whether you believe that any other risks should be included in the overall risk assessment when considering all indications for this device type.**
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 controls are sufficient to provide reasonable assurance of its safety and effectiveness or that application of special controls would provide such assurance, AND
 - the device is life-supporting or life-sustaining, 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.
- a. **FDA believes that general controls alone are not sufficient to provide a reasonable assurance of safety and effectiveness for urogynecologic surgical mesh instrumentation. If you disagree, please discuss how general controls alone are sufficient to provide a reasonable assurance of safety and effectiveness for this device type. General controls may include:**
- i. **Prohibition against adulterated or misbranded devices,**
 - ii. **Good Manufacturing Practices (GMP),**
 - iii. **Registration of manufacturing facilities,**
 - iv. **Listing of device types,**
 - v. **Record keeping, etc.**
- b. **FDA does not believe that urogynecologic surgical mesh instrumentation is “life-supporting or life-sustaining, or of substantial importance in preventing impairment of human health.” Do you agree with this assessment? If not, please explain why.**
- c. **FDA does not believe that urogynecologic surgical mesh instrumentation presents a “potential unreasonable risk of illness or injury” Do you agree with this assessment? If not, please explain why.**
- d. **FDA believes sufficient information exists to establish special controls for urogynecologic surgical mesh instrumentation. Based on the information presented today, please discuss whether you believe that sufficient information exists to establish special controls that can provide a reasonable assurance of safety and effectiveness for this device type.**
3. FDA proposes the following special controls for urogynecologic surgical mesh instrumentation to provide reasonable assurance of their safety and effectiveness.
- The device must be demonstrated to be biocompatible;
 - The device must be demonstrated to be sterile, including adequate reprocessing for reusable devices;

- Performance data must support the shelf life of the device by demonstrating package integrity and device functionality over the requested shelf life;
- Non-clinical performance testing must demonstrate that the device meets all design specifications and performance requirements, and that the device performs as intended under anticipated conditions of use; and
- Labeling must include:
 - Information regarding the mesh design that may be used with the device;
 - Detailed summary of the clinical evaluations pertinent to use of the device;
 - Expiration date; and
 - Where components are intended to be sterilized by the user prior to initial use and/or are reusable, validated methods and instructions for sterilization and/or reprocessing of any reusable components.

Please discuss whether these special controls appropriately mitigate the identified risks to health of this device type, and whether you recommend additional or different special controls.