

General and Plastic Surgery Devices Advisory Committee Meeting

Integra LifeSciences Corporation

SurgiMend PRS Acellular Bovine Dermal Matrix

(SurgiMend PRS ABDM)

October 20, 2021

1. The sponsor performed, or plans to perform, non-clinical evaluations including biocompatibility and mechanical testing. In addition, clinical data were provided. Please comment on whether additional animal studies are necessary to address the time course of product absorption and tissue response to the implanted device when used next to a tissue expander or breast implant.
2. The sponsor plans to perform mechanical compatibility testing with a textured tissue expander and a smooth breast implant device. Please comment on whether additional non-clinical studies are necessary to evaluate mechanical compatibility of SurgiMend PRS ABDM with the existing range of tissue expander and breast implant devices.
3. Does the Advisory Committee believe a post-approval study is needed for the SurgiMend PRS ABDM (if approved)? If a post-approval study is needed, is the proposed post-approval study acceptable? If not, please recommend changes to the proposed post-approval study.

Note: The requested discussion item related to the proposed post-approval study should not be interpreted to mean that FDA has made a decision or is making a recommendation on the approvability of this PMA. The presence of a post-approval study plan or commitment does not alter the requirements for premarket approval and a recommendation from the Panel on whether the benefits of the device outweigh the risks. The pre-market data must reach the threshold for providing a reasonable assurance of safety and effectiveness before the device can be found approvable and any post-approval study could be considered.

VOTING

Indication for Use: SurgiMend PRS Acellular Bovine Dermal Matrix is indicated for use as soft tissue support in post-mastectomy breast reconstruction. SurgiMend PRS Acellular Bovine Dermal Matrix is specifically indicated for: Immediate, two-stage, submuscular, alloplastic breast reconstruction.

4. VOTE: Is there reasonable assurance that the SurgiMend PRS ABDM is safe for the proposed Indications for Use?
5. VOTE: Is there reasonable assurance that the SurgiMend PRS ABDM is effective for the proposed Indications for Use?

6. VOTE: Do the benefits of the SurgiMend PRS ABDM outweigh the risks for the proposed Indications for Use?