24 Hour Summary
General and Plastic Surgery Devices
Advisory Committee Meeting
October 20, 2021

Introduction:

On October 20, 2021, the committee discussed, made recommendations, and voted on information regarding the premarket approval application (PMA) for the SurgiMend PRS Acellular Bovine Dermal Matrix (SurgiMend PRS ABDM) by Integra LifeSciences Corporation.

The sponsor proposed the following Indications for Use:

SurgiMend PRS Acellular Bovine Dermal Matrix is intended 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.

Panel Deliberations/FDA Questions:

Question 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.

The panel agreed that no 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. The panel highlighted their desire for additional clinical evidence during this discussion.

Question 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.

The Panel's consensus was that additional non-clinical studies were not necessary to evaluate mechanical compatibility of SurgiMend PRS ABDM with the existing range of tissue expander and breast implant devices. However, it was noted that plastic surgeons are moving away from textured devices. The panel suggested that mechanical testing should include testing with a

smooth tissue expander and highlighted their desire for additional clinical evidence, including histology of biopsies at the time of implant exchange

Question 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.

The Advisory Committee agreed that a post-approval study (PAS) would be needed for the SurgiMend PRS ABDM (if approved).

- The panel recommended conducting a larger randomized controlled trial with SurgiMend with more data than was made available by the MROC database including information on surgeons, sites, surgeon reported outcome measure, and details of adjuvant therapy (such as timing).
- Panel recommended that tissue samples/biopsies taken at the time of tissue expander implant exchange be used to assess histology and cytology.
- The panel recommended that subjects be followed for at least 5 years following the first surgery. Panel members also recommended that follow up be very high (at or above 90% complete data) and recommended serious consideration of withdrawal of approval if lower follow up rates are observed. The Panel identified that high follow up rates are common in studies with cancer patients and suggested recruiting oncologists in addition to plastic surgeons.
- The panel recommended that use of any ADM or mesh in breast reconstruction include an Informed Consent/Decision process for patients in clinical practice as patients may be unaware if they are receiving a mesh device as part of their breast reconstruction.
- The panel recommended the use of Unique Device Identifiers (UDI) as part of data collected in a PAS, labeling and adverse event reporting.
- The panel recommended consideration of different effectiveness outcomes for the PAS, including cosmesis and surgeon reported outcomes to be assessed in addition to patient reported outcomes.

Panel Vote:

The Panel voted on the safety, effectiveness, and benefit-risk profile of the SurgiMend PRS ABDM device.

VOTE 1: The Panel voted **7 Yes; 5 No; 0 Abstentions** that there is a reasonable assurance that the SurgiMend PRS ABDM is safe for the proposed Indications for Use.

VOTE 2: The Panel voted **5 Yes; 6 No; 1 Abstention** that there is a reasonable assurance that the SurgiMend PRS ABDM is effective for the proposed Indications for Use.

VOTE 3: The Panel voted **5 Yes; 7 No; 0 Abstentions** that the benefits of the SurgiMend PRS ABDM outweigh the risks for the proposed Indications for Use.

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