24 Hour Summary
General and Plastic Surgery Devices
Advisory Committee Meeting
October 26, 2022

Introduction:

A meeting of the General and Plastic Surgery Devices Panel ("the Panel") of the Medical Devices Advisory Committee was convened on October 26, 2022, to discuss and make recommendations related to classification of nine unclassified, preamendments device types.

On October 26, 2022, in Session I, the Panel first discussed and made recommendations regarding the classification of tissue expanders and accessories, which are currently unclassified preamendments devices, to (1) Class III (premarket approval) when intended for use in the breast, (2) Class II (general and special controls) when intended for use in other parts of the body (non-breast) and (3) Class II (general and special controls) for tissue expander accessories. In Session II, the Panel discussed and made recommendations regarding the classification of mammary sizers, which are currently unclassified preamendments devices, to II (general and special controls). In Session III, the Panel discussed and made recommendations regarding the classification of wound dressings with animal-derived material(s), which are currently unclassified preamendments devices, to class II (general and special controls). In Session IV, the Panel discussed and made recommendations regarding the classification of absorbable synthetic wound dressings, which are currently unclassified preamendments devices, to class II (general and special controls). In Session V, the Panel discussed and made recommendations regarding the classification of topical hemostatic wound dressing without thrombin and topical hemostatic wound dressing with licensed thrombin, which are currently unclassified preamendments devices, to class II (general and special controls).

Panel Deliberations/FDA Questions:

Session I

The Panel discussed the following FDA-identified risks to health for tissue expanders intended for use in the breast:

- Skin trauma
- Device malfunction or device failure leading to reoperation
- Adverse tissue reaction
- Infection
- Pain or discomfort
- Delay in adjunctive treatment or therapies
- Breast Implant Illness (BII)
- Breast Implant- Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

The Panel agreed with inclusion of the above FDA-identified risks in the overall risk assessment of tissue expanders intended for use in the breast under product code "LCJ". The Panel also recommended:

- The possibility of rib fractures
- The risk of delayed ability to undergo various diagnostic and treatment modalities due to the presence of the tissue expander, including the inability to use MRI and a delay in oncological treatments
- That the potential risks be further described as to whether they are attributed to the device itself or the surgical procedure.

The panel discussed whether there is reasonable assurance of safety for tissue expanders intended for use in the breast.

The panel discussed whether there is a reasonable assurance of effectiveness for tissue expanders intended for use in the breast.

The panel discussed whether the risk of injury is unreasonable given the lack of probable benefit for tissue expanders intended for use in the breast.

The panel had mixed recommendations on the FDA's proposed classification of class III (PMA), as 7 felt class II is appropriate and 10 felt that class III is appropriate.

It was agreed that the panel does not wish to see any sort of reduction in availability due to a potential up-classification.

The panel discussed whether the previously identified risks would also apply to other tissue expanders intended for use in the breast, regardless of technological characteristics. The panel in general agreed that the tissue expanders for other locations in the body should be the same classification as those in the breast.

The Panel discussed the following FDA-identified risks to health for tissue expanders intended for use in other parts of the body (non-breast) under product code "LCJ:

- Skin trauma
- Device malfunction or device failure leading to reoperation
- Infection
- Adverse tissue reaction
- Pain or discomfort

In general, the panel suggested that the risks based upon placement in other parts of the body was no different than those identified for devices used in the breast.

The Panel discussed the identified special controls and whether they appropriately mitigate the identified risks to health, or if additional or different special controls were necessary. The Panel generally agreed with the identified special controls as proposed.

The Panel disagreed with the FDA's proposed classification of class II (special controls) for tissue expanders intended for use in other parts of the body (non-breast) as they feel it should be the same classification as for breast implantation.

The Panel discussed the following FDA-identified risks to health for tissue expander accessories under product code "LCJ":

- Skin trauma
- Device malfunction or device failure leading to reoperation
- Infection
- Adverse tissue reaction
- Pain or discomfort

The Panel discussed the identified special controls and whether they appropriately mitigate the identified risks to health, or if additional or different special controls were necessary. The Panel generally agreed with the identified special controls as proposed.

The Panel agreed with the FDA's proposed classification of class II (special controls) for tissue expander accessories.

Session II

The Panel discussed the following FDA-identified risks to health for mammary sizers:

- Adverse tissue reaction
- Infection
- Device malfunction leading to increased operative time
- Use error/Improper device use

The Panel agreed with inclusion of the above FDA-identified risks in the overall risk assessment of mammary sizers under product code "MRD".

The Panel discussed the identified special controls and whether they appropriately mitigate the identified risks to health, or if additional or different special controls were necessary. The Panel generally agreed with the identified special controls as proposed.

The Panel generally agreed with the FDA's proposed classification of class II (general and special controls).

Session III

The Panel discussed the following FDA-identified risks to health for wound dressings with animal-derived material(s):

- Adverse Tissue Reaction
- Infection
- Immunological reaction
- Transmission of pathogens and parasites
- Delays in wound healing

The Panel agreed with inclusion of the above FDA-identified risks in the overall risk assessment of wound dressings with animal-derived material under product code "KGN", but also noted the need to identify the species of the animal from which the animal components were derived in the labeling and to clearly define the scope of 'animal-derived material'.

The Panel discussed the identified special controls and whether they appropriately mitigate the identified risks to health, or if additional or different special controls were necessary. The Panel unanimously/generally agreed that the identified proposed special controls adequately covered the risks and safety concerns discussed.

The Panel generally agreed with the FDA's proposed classification of class II (general and special controls).

Session IV

The Panel discussed the following FDA-identified risks to health for absorbable synthetic wound dressings:

- Toxicity
- Adverse tissue reaction
- Infection
- Delays in wound healing
- Failure of device integration

The Panel agreed with inclusion of the above FDA-identified risks in the overall risk assessment of absorbable synthetic wound dressings under product code "FRO".

The Panel discussed the identified special controls and whether they appropriately mitigate the identified risks to health, or if additional or different special controls were necessary. The Panel generally agreed that the identified proposed special controls adequately covered the risks and safety concerns discussed. The Panel also noted that the identification of toxicity is

too broad and should be more specific. In addition, the Panel noted that scaffold claims relating to cellular infiltration may be misleading as they may imply promotion of wound healing which is outside the scope of the intended use of these products.

The Panel unanimously agreed with the FDA's proposed classification of class II (general and special controls).

Session V

The Panel discussed the following FDA-identified risks to health for topical hemostatic wound dressings without thrombin and with licensed thrombin:

- Uncontrolled bleeding
- Infection
- Adverse tissue reaction
- Delay in wound healing
- Transmission of pathogens and parasites
- Immunological reaction
- Microbial growth within the product during use
- Contribution to the spread of antimicrobial resistance (AMR)
- Foreign body reaction due to retained device
- Rebleeding after attaining hemostasis
- Arterial or venous embolism
- Thrombosis (e.g., deep vein thrombosis (DVT))

The Panel agreed with inclusion of the above FDA-identified risks in the overall risk assessment of topical hemostatic wound dressings without thrombin and with licensed thrombin.

The Panel discussed the identified special controls for topical hemostatic wound dressing devices **without thrombin** and whether they appropriately mitigate the identified risks to health, or if additional or different special controls were necessary. The Panel unanimously agreed that the identified proposed special controls adequately covered the risks and safety concerns discussed.

The Panel discussed the identified special controls for topical hemostatic wound dressing devices **with licensed thrombin** and whether they appropriately mitigate the identified risks to health, or if additional or different special controls were necessary. The Panel unanimously agreed that the identified proposed special controls adequately covered the risks and safety concerns discussed.

The Panel unanimously agreed with the FDA's proposed classification of class II (general and special controls).

Open Public Hearing (OPH)

In the morning OPH session, the Panel heard presentations from clinicians and other stakeholders. Ms. Maria Gmitro, speaking on behalf of the Breast Implant Safety Aliance (BISA), Joan Melendez, speaking on behalf of XCELERATE UDI. Inc., Dr. Bernard Lee presenting on behalf of the American Society of Plastic Surgeons under The Plastic Surgery Foundation, and Ms. Madris Kinard of Device Events discussed tissue expanders.

In the afternoon OPH sessions, the Panel heard from Dr. Diana Zuckerman, speaking on behalf of the National Center for Health Research, who discussed wound dressings.

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Transcripts:

Transcripts may be downloaded from:
October 26-27, 2022: General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee Meeting Announcement - 10/26/2022 | FDA

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