510(K) SUMMARY

Applicant: Ethicon Inc.
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Trade Device Name: EVICEL™ Laparoscopic Airless Spray Accessory (35 cm Rigid)

Common Device Name: Fibrin Sealant Preparation Device

Product Code: MZM

Classification name: Piston Syringe (21 CFR 880.5860)

Primary Predicate Device: EVICEL™ Airless Spray Accessory – BK140093

Secondary Predicate Device: EVICEL™ 35 cm Rigid Tip Accessory – K070575

Manufacturer: Omrix Biopharmaceuticals LTD
MDA Blood Center Sheba Hospital
Ramat Gan Israel5510801

Establishment Number: 3003183625

Description of the Device Subject to Premarket Notification:

The EVICEL™ Laparoscopic Airless Spray Accessory (35 cm Rigid) device is a new accessory device that connects to the current EVICEL™ Application Device, allowing EVICEL® Fibrin Sealant (BLA125010) to be dripped or sprayed laparoscopically/endoscopically without the use of an external CO_2 source. The EVICEL™ Laparoscopic Airless Spray Accessory (35 cm Rigid) device will combine technologies of the previously 510(k) cleared EVICEL™ Airless Spray Accessory (BK140093) and the EVICEL™ 35 cm Rigid Tip Accessory (K070575).

Indications for Use:

The EVICEL™ Laparoscopic Airless Spray Accessory (35 cm Rigid) is intended to be used with the EVICEL™ Application Device for the simultaneous topical application of the two biological components of EVICEL® Fibrin Sealant (Human) onto the surface.

Summary of Technological Characteristics of New Device to Predicate Device:

The principle of operation and fundamental scientific technology of the EVICEL™ Application Device has not changed and remains the same as described in the primary predicate submission BK140093. Additionally, there are no changes to the existing accessory tips that are currently marketed for use with the EVICEL™ Application Device. These tips include the 6-cm tip which is pre-packaged with the Application Device, the 35-cm tip, 45 cm tip, 4 cm Control tip and the Airless Spray Accessory tip. All tips, when used as intended, enable mixing of the biological components of the fibrin sealant, either within the accessory tip or upon expression, to enable the formation of the fibrin clot on the tissue surface.

The EVICEL™ Laparoscopic Airless Spray Accessory (35 cm Rigid) device is an additional tip that allows the user to manually express EVICEL® Fibrin Sealant and yield a spray in the absence of gas assistance (CO_2) in laparoscopic/endoscopic procedures. This atomization of the fibrin sealant is similar in spray manner to when compared to the existing Airless Spray Accessory tip or 35 cm Rigid Tip Accessory, with CO_2 assistance. The EVICEL™ Laparoscopic Airless Spray Accessory (35 cm Rigid) will also provide fibrin sealant via drip method, when the EVICEL™ Airless Spray Accessory spray tip is removed, similar to the existing EVICEL™ 35 cm Rigid Tip Accessory. The expression of the fibrin sealant is through manual depression of the plunger on the EVICEL™ Application Device which remains unchanged.

Performance Data:

There were no changes to the EVICEL™ Application Device or currently marketed accessory tips; therefore, further performance testing was not required on these components.

The EVICEL™ Laparoscopic Airless Spray Accessory (35 cm Rigid) underwent extensive performance testing to support adherence to device requirements as defined in user specifications. This testing demonstrated intended performance and substantial equivalence to the predicate devices.

Performance Testing included:

Sterilization
The EVICEL™ Laparoscopic Airless Spray Accessory (35 cm Rigid) device undergoes (b) (4) sterilization.

Per ISO 11137 requirements, minimum sterilization dose establishment and dose mapping activities were completed to confirm that the EVICEL™ Laparoscopic Airless Spray Accessory (35 cm Rigid) device can be successfully irradiated within a controlled dose range to achieve a minimum Sterility Assurance Level (SAL) of (b) (4) per (b) (4) and (b) (4). The sterilization (b) (4) is (b) (4). ISO 11137-2 Method (b) (4) was used for establishing the minimum sterilization (b) (4) for the EVICEL™ Laparoscopic Airless Spray Accessory (35 cm Rigid) device.

The sterilization protocol and acceptance criteria were based on the requirements described in ISO 11137-1 and ISO 11137-2. The sterilization process was validated in compliance with the requirements of ISO 11137-1:2006/(R)2010, ISO 11137-2:2013 and ISO 11137-3:2006 (Guidance).

Endotoxin
Per FDA Guidance, "Submission and Review of Sterility Information in Premarket Notification 510(k Submissions for Devices Labeled as Sterile," the EVICEL™ Laparoscopic Airless Spray Accessory (35 cm Rigid) device is considered a general medical device (e.g., blood contacting and/or implanted) that requires endotoxin testing; however, it is not intended to contact cerebrospinal fluid (CSF) and therefore the endotoxin limit is less than or equal to 20 EU/Device per FDA Guidance for Industry Pyrogen and Endotoxins Testing: Questions and Answers, June 2012. Bacterial Endotoxin Testing (BET), specifically a (b) (4) test method, was used to make the determination that the device meets the endotoxin specification. Testing utilized validated methods that are in compliance with (b) (4) and (b) (4).

Packaging
The EVICEL™ Laparoscopic Airless Spray Accessory (35 cm Rigid) package system underwent transportation testing to ensure the package integrity is maintained. All acceptance criteria were met in accordance to ISO 11607-1, Packaging for Terminally Sterilized Medical Devices. The methodology followed the below consensus standards:

- ISO11607-1:2009+A1:2014 Packaging for Terminally Sterilized Medical Devices Part 1: requirements for materials, sterile barrier systems and packaging systems
- (b) (4)
- (b) (4)
- (b) (4)

- (b) (4)
- (b) (4)

Shelf Life

Test results support the shelf life label claim. The methodology followed the below consensus standards:

- ISO11607-1:2009+A1:2014 Packaging for Terminally Sterilized Medical Devices Part 1: requirements for materials, sterile barrier systems and packaging systems
- (b) (4)
- Guidance for Industry: Container and Closure System Integrity Testing In lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products, FDA, February 2008.
- (b) (4)
- (b) (4)

Human Factors

During the development of the EVICEL™ Laparoscopic Airless Spray Accessory (35 cm Rigid) device, Formative Evaluations and Human Factors Validation were conducted in compliance with (b) (4) and in accordance with the Guidance for Industry and Food and Drug Administration Staff: Applying Human Factors and Usability Engineering to Medical Devices (2016). The EVICEL Laparoscopic Airless Spray Accessory was found to be safe and effective for intended users, uses, and use environments. In addition, a Usability Summary Report detailed usability activities and met the requirements as outlined in the aforementioned Guidance and Standard.

Biocompatibility

Biocompatibility of device, components and packaging materials were tested and passed the below consensus standards. This assessment was conducted in conjunction with the FDA Guidance on the use of ISO 10993-1 (2009).

- EN ISO 10993-18: 2009 Material Characterization
- EN ISO 10993-17:2009 Toxicological Evaluation of Extractables
- EN ISO 10993-5: 2009 Cytotoxicity
- EN ISO 10993-10: 2010 Sensitization
- EN ISO 10993-10: 2010 Irritation/ Intracutaneous Reactivity
- EN ISO 10993-11: 2009 Acute Systemic Toxicity
- EN ISO 10993-11: 2009 Pyrogenicity (Material Mediated)
- EN ISO 10993-4: 2009 Hemocompatibility (Hemolysis)

- EN ISO 10993-4: 2009 Hemocompatibility (Partial thromboplastin)
- (b) (4) Biocompatibility of Medical Device Packaging Materials
- EN ISO 10993-1: 2009 Biocompatibility risk assessment

Performance Bench Testing

Device verification and bench testing was performed to ensure that the new accessory meets the customer and design requirements and the performance is substantially equivalent to the existing EVICEL™ Airless Spray Accessory tip (for spray method) and EVICEL™ 35 cm Rigid Tip Accessory (for drip method).

- *Device Verification/Bench Testing utilized the following internal test methods:*
  - (b) (4)
  - (b) (4)
  - (b) (4)
  - (b) (4)
  - (b) (4)
    - (b) (4)
    - (b) (4)
    - (b) (4)

Preclinical Testing

A Time to Hemostasis Study was done in mature swine to ensure that the new accessory tip does not impact performance of the fibrin sealant as compared to the existing predicate devices.

Conclusion:

Performance testing demonstrated that the EVICEL™ Laparoscopic Airless Spray Accessory (35 cm Rigid) device substantially equivalent to the EVICEL™ Airless Spray Accessory, in spray mode, and EVICEL™ 35 cm Rigid Tip Accessory, in drip mode. There was no change to the intended use of the EVICEL™ Application Device and existing accessory tips. Thus, we conclude that the EVICEL™ Laparoscopic Airless Spray Accessory (35 cm Rigid) device is substantially equivalent to the cited predicate devices.