510(k) Summary

I. SUBMITTER

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II. DEVICE

Trade Device Name:	VISTASEAL™ Laparoscopic Dual Applicator (35 cm Rigid) VISTASEAL™ Laparoscopic Dual Applicator (45 cm Flexible
Common Device Name:	Fibrin Sealant Preparation Device
Classification Name:	Piston Syringe
Regulatory Class:	II
Regulation:	21 CFR 880.5860
Product Code:	MZM

III. PREDICATE DEVICE

Primary Predicate Device:	EVICEL® Laparoscopic Airless Spray Accessory (35 cm Rigid) BK170138
Secondary Predicate Device:	EVICEL® Application Device (EVICEL Application Device Soft Tip Accessory) K070575

The Predicate Devices have not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The VISTASEAL Laparoscopic Dual Applicator (35 cm Rigid and 45cm Flexible) are single-use devices designed for the simultaneous topical application of the two biological components of the VISTASEAL Fibrin Sealant (Human) onto the surface. The application can be accomplished by dripping or spraying (without the use of pressurized CO_2) the Fibrin Sealant. The VISTASEAL Laparoscopic Dual Applicator (35 cm Rigid and 45cm Flexible) devices will be supplied as an accessory tip that can be attached to the VISTASEAL Adapter by two Luer Locks. The proposed devices will be provided in a thermoformed tray with a Tyvek lid, along with two spare Spray Tips.

The VISTASEAL Laparoscopic Dual Applicator (35 cm Rigid and 45cm Flexible) devices with the VISTASEAL Adapter, will connect to the VISTASEAL Fibrin Sealant (Human) Syringe Holder. Once connected, the user can manually depress the plunger to either spray or drip (when the Spray Tip is removed) the VISTASEAL Fibrin Sealant (Human).

V. INDICATIONS FOR USE

The VISTASEAL™ Laparoscopic Dual Applicator (35 cm Rigid or 45 cm Flexible) is intended to be used with the VISTASEAL™ Dual Applicator for the simultaneous topical application of the two biological components of VISTASEAL Fibrin Sealant (Human) onto the surface.

The Indications for Use is identical to the primary predicate device, except for the name of the Fibrin Sealant (Human) that is cross-referenced. This difference does not alter the intended therapeutic use of the device nor does it affect the safety and effectiveness of the device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The VISTASEAL Laparoscopic Dual Applicator (35 cm Rigid and 45cm Flexible) devices have the same fundamental scientific technology as the predicate devices. Both the proposed and predicate devices, when used as intended, mix the biological components of the Fibrin Sealant either within the tip (during praying) or upon exiting the tip (during dripping) and enable the formation of the fibrin clot onto the tissue surface. The application of the Fibrin Sealant is through manual depression of the plunger which is identical to the predicate devices. The biologic with which the devices are intended to be used has changed from EVICEL Fibrin Sealant (Human) to VISTASEAL Fibrin Sealant (Human).

The VISTASEAL Laparoscopic Dual Applicator (35 cm Rigid and 45cm Flexible) devices have the same Technological Characteristics as the Predicate EVICEL Laparoscopic Airless Spray Accessory (BK170138) as follows:

1) Drip the Fibrin Sealant when the pre-attached Spray Tip is removed
2) Spray the Fibrin Sealant without the use of pressurized CO_2
3) The Fibrin Sealant is delivered by manually depressing the plunger
4) During spraying, the two components of the Fibrin Sealant are mixed prior to exiting the Spray Tip.
5) Use the same design and materials for the Spray Tips
6) Sterile, single use and non-pyrogenic

The VISTASEAL Laparoscopic Dual Applicator (35 cm Rigid and 45cm Flexible) devices have the same Technological Characteristics as the Predicate EVICEL Application Device (EVICEL Application Device Soft Tip Accessory) (K070575) as follows:

1) Drip the Fibrin Sealant. For the Subject Device, this is achieved when the pre-attached Spray Tip is removed
2) Spray the Fibrin Sealant. For the Subject Devices, this is achieved without the use of pressurized CO_2
3) The Fibrin Sealant is delivered by manually depressing the plunger
4) The Fibrin Sealant is mixed upon exiting the device
5) Flexible, 45 cm long tip
6) Sterile, single use and non-pyrogenic

VII. PERFORMANCE DATA

The VISTASEAL Dual Applicator (35 cm Rigid and 45 cm Flexible) devices' design verification and validation were performed to demonstrate the design requirements were met. The testing also supports substantial equivalence to the predicate devices.

Biocompatibility

Biocompatibility of the materials for the VISTASEAL Dual Applicator (35 cm Rigid and 45cm Flexible) device was assessed in accordance with ISO 10993-1 and the FDA Guidance document on Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (2016). The assessments demonstrated that there were no biocompatibility risks associated with the materials selected.

- Cytotoxicity: ISO 10993-5, Biological evaluation of medical devices- Part 5: Tests for *in vitro* cytotoxicity (2009)
- Sensitization: ISO 10993-10, Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization (2010)
- Irritation/Intracutaneous Reactivity: ISO 10993-10, Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization (2010)
- Acute Systemic Toxicity: ISO 10993-11, Biological evaluation of medical devices -Part 11: Tests for systemic toxicity (2006)
- Endotoxin/Pyrogenicity: USP <161> Transfusion and Infusion Assemblies and Similar Medical Devices Endotoxin and Pyrogen, USP <151> Pyrogenicity Test, AAMI ST72:2011 Bacterial Endotoxins Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing, 10993-11, Biological evaluation of medical devices- Part 11: Tests for systemic toxicity (2006)

- Hemocompatibility – Hemolysis: ASTM F756, Standard Practice for Assessment of Hemolytic Properties of Materials (2017) and ISO 10993-4, Biological evaluation of medical devices- Part 4: Selection of tests for interactions with blood (2017)
- Hemocompatibility – Partial Thromboplastin Time: ASTM F2382: Standard Test Method for Assessment of Circulation Blood-Contacting Medical Device Materials on Partial Thromboplastin Time (PTT) (2017)

Although not required, hemocompatibility tests were performed as some of the device components have direct contact with the Fibrin Sealant. These tests demonstrated that device materials are acceptable for the delivery of the Fibrin Sealant.

Sterilization

The VISTASEAL Laparoscopic Dual Applicator (35 cm Rigid and 45cm Flexible) devices will be provided as sterile with a Sterility Assurance Level of 10^{-6} and for single use only and meets the requirements of EN ISO 11137, "Sterilization of Health Care Products – Requirements for Validation and Routine Control – Radiation Sterilization". The VISTASEAL Laparoscopic Dual Applicator (35 cm Rigid and 45cm Flexible) devices will be sterilized with gamma irradiation and per ISO 11137-1:2013 and ISO 11137-3:2006. Routine bioburden and bacterial endotoxin testing will be performed for this device.

Shelf Life

The shelf life of the VISTASEAL Laparoscopic Dual Applicator (35 cm Rigid and 45 cm Flexible) devices are support by both accelerated and real-time aging. The initial shelf life of the devices will be one year. In has also been demonstrated that the sterile barrier for the VISTASEAL Laparoscopic Dual Applicator (35 cm Rigid and 45 cm Flexible) devices will be maintained throughout the stated shelf life.

Transit Testing / Packaging Integrity

Transit testing demonstrates that the packaging maintains its integrity as well as device functionality. The following tests were performed:

1) Visual Inspection
2) Sterile Barrier Integrity
3) Seal Strength
4) Device Functionality

Bench-top Testing

Bench-top testing and device verification activities were performed to demonstrate that the design requirements were met and that the VISTASEAL Laparoscopic Dual Applicator (35 cm Rigid and 45 cm Flexible) devices.

The following tests were performed utilizing internal test methods:

- Torque Testing
- Coverage Area
- Leak testing
- Tension Testing
- Grasper Compatibility
- Expression Force
- Spray Tip Wiping
- Trocar Compatibility
- Compatibility with the Fibrin Sealant

Human Factors and Usability

Human Factors Validation was conducted in compliance to and following the Guidance for Industry and Food and Drug Administration Staff: Applying Human Factors and Usability Engineering to Medical Devices (2016). The VISTASEAL Laparoscopic Dual Applicator (35 cm Rigid and 45 cm Flexible) devices were found to be safe and effective for intended users, uses, and use and demonstrated that the requirements were met.

VIII. CONCLUSION

The VISTASEAL Laparoscopic Dual Applicator (35 cm Rigid and 45 cm Flexible) devices are substantially equivalent to the predicate devices as the intended use and fundamental scientific principles are the same. Furthermore, performance testing demonstrated that the VISTASEAL Laparoscopic Dual Applicator (35 cm Rigid and 45 cm Flexible) devices are substantially equivalent to the predicate EVICEL Laparoscopic Airless Spray Accessory (35 cm Rigid) and EVICEL® Application Device (EVICEL Application Device Soft Tip) Accessory through its drip and spray application of Fibrin Sealant and does not raise any new concerns of safety and efficacy. Thus, we conclude that the VISTASEAL Laparoscopic Dual Applicator (35 cm Rigid and 45 cm Flexible) devices are as safe, as effective and performs as well as the predicate devices and that substantial equivalence is demonstrated under the Federal Food, Drug, and Cosmetic Act.