August 2, 2023

E Surgical, LLC
% Mr. Craig Coombs
President
Coombs Medical Device Consulting, Inc
1100 Pacific Marina, Suite 806
Alameda, California 94501

Re: K231126
Trade/Device Name: Eblator Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 18, 2023
Received: April 20, 2023

Dear Mr. Coombs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.08.02 08:05:27 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231126

Device Name
Eblator Device

Indications for Use *(Describe)*
The Eblator Device is intended for general arthroscopic applications, which include cutting, vaporization, and coagulation. This device is intended to be used in conjunction with a general purpose electrosurgical generator via a standard active lead and a standard return lead connection. The device is only operable when activated in an appropriate conductive media, such as a standard saline solution.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary: K231126

A. Device Information:

Category	Comments
Sponsor:	E SURGICAL, LLC 150 Isidor Court Unit 203 Sparks, Nevada 89441
Correspondent Contact Information:	Mr. Craig Coombs President Coombs Medical Device Consulting 1100 Pacific Marina, Suite 806 Alameda, California 94501 Tel: 650-380-2474 Email: CraigJCoombs@gmail.com
Device Common Name:	Electrosurgical Ablator
Device Classification Number:	21 CFR 878.4400
Device Classification & Product Code:	Class II, GEI
Device Proprietary Name:	Eblator Device

Predicate Device Information:

Predicate Device 1:	Bovie Disposable Bipolar Ablator
Predicate Device 1 Manufacturer:	Bovie Medical Corporation
Predicate Device 1 Common Name:	Electrosurgical Ablator
Predicate Device 1 Premarket Notification #	K152777
Predicate Device 1 Classification:	21 CFR 878.4400 Electrosurgical, Cutting & Coagulation Device and Accessories
Predicate Device 1 Classification & Product Code:	Class 2, GEI

Predicate Device 2:	Bovie Disposable Bipolar Ablator
Predicate Device 2 Manufacturer:	Bovie Medical Corporation
Predicate Device 2 Common Name:	Electrosurgical Ablator
Predicate Device 2 Premarket Notification #	K161558
Predicate Device 2 Classification:	21 CFR 878.4400 Electrosurgical, Cutting & Coagulation Device and Accessories
Predicate Device 2 Classification & Product Code:	Class 2, GEI

B. Date Summary Prepared

1 August 2023

C. Description of Device

The application device, the Eblator Device, is an electrosurgical ablator for general arthroscopic applications. In conjunction with a general purpose electrosurgical generator, the Eblator Device provides cutting, vaporization and coagulation of target tissue by radio frequency electrosurgical energy. As with most hand-controlled surgical pencils, the Eblator Device can also be used with footswitch control when a footswitch is connected to a generator designed for footswitch control.

The Eblator Device is requesting clearance for 4 models of Eblator Device, representing different combinations of electrode configurations and aspiration design. The Eblator Device models include 2 different electrode angles, 90^{o} and 50^{o}, as well as with or without aspiration design. Except for these characteristics, these 4 models are all identical.

The Eblator Device is designed to be used with a compatible electrosurgical generator and aspiration system (aspiration model only).

These devices are single use and are sold sterile.

D. Indications for Use

The Eblator Device is intended for general arthroscopic applications, which include cutting, vaporization, and coagulation. This device is intended to be used in conjunction with a general purpose electrosurgical generator via a standard active lead and a standard return lead connection. The device is only operable when activated in an appropriate conductive media, such as a standard saline solution.

E. Comparison to Predicate Device

Feature	**Application Device:** *Eblator Device*	**Predicate Device:** Bovie Disposable Bipolar Ablator (K152777)	**Predicate Device:** Bovie Disposable Bipolar Ablator (K161558)	**Pertinence of Feature to Consideration of Substantial Equivalence.**
Indications for Use	The Eblator Device is intended for general arthroscopic applications, which include cutting, vaporization, and coagulation. This device is intended to be used in conjunction with a general purpose electrosurgical generator via a standard active lead and a standard return lead connection. The device is only operable when activated in an appropriate conductive media, such as a standard saline solution.	This device is intended to be used for cutting, vaporization, and coagulation of soft tissue during arthroscopic surgical procedures. This device is intended to be used with a standard electrosurgical generator with footswitch control and a standard return electrode connection, and the electrode is to be activated only when immersed in a conductive media such as standard saline solution.	Same as K152777	The difference is that the compatible electrosurgical generator used with the predicates must have a footswitch pedal. The application device uses its integrated hand switch or a footswitch to control the current. As this difference does not impact the safety and efficacy of the device, it is determined the indication for use for these three devices are identical.
Product Code	GEI	GEI	GEI	Identical
Model Versions	***RB4050A-01:*** 4.0 mm 50°Aspirating Bipolar Ablator, Single Use	***BA3350A:*** 3.3 mm Disposable Bipolar Ablator 50°, Aspirating	***BA2455NA:*** 2.4 mm Disposable Bipolar Ablator 55°, Non-Aspirating	The application device presents a subset of models that are present in the predicate devices.
	RB4050-01: 4.0 mm 50° Bipolar Ablator, Single Use	***BA3350NA:*** 3.3 mm Disposable Bipolar Ablator 50°, Non-Aspirating	***BA1860NA:*** 1.8 mm Disposable Bipolar Ablator 60°, Non-Aspirating	
	RB4090A-01: 4.0 mm 90° Aspirating Bipolar Ablator, Single Use		***BA3390A:***	

Feature	**Application Device:** *Eblator Device*	**Predicate Device:** Bovie Disposable Bipolar Ablator (K152777)	**Predicate Device:** Bovie Disposable Bipolar Ablator (K161558)	**Pertinence of Feature to Consideration of Substantial Equivalence.**
			3.3 mm Disposable Bipolar Ablator 90°, Aspirating	
	RB4090-01: 4.0 mm 90° Bipolar Ablator, Single Use		***BA3390NA:*** 3.3 mm Disposable Bipolar Ablator 90°, Non-Aspirating	
Technology				
Energy Use	Radiofrequency	Same	Same	Identical
Operation Principle	Use RF power to generate arcing through bubbles formed between an active electrode and tissue with the tissue being vaporized by the arcing.	Same	Same	Identical
Equipment Mated	General purpose electrosurgical generator with standard return electrode connection. Compatible foot switch controller is optional. **Aspiration**: Adequate vacuum source for procedure	Standard electrosurgical generator with and standard return electrode connection. Compatible foot switch controller is required. **Aspiration**: Adequate vacuum source for procedure	Standard electrosurgical generator with standard return electrode connection. Compatible foot switch controller is required. **Aspiration**: Adequate vacuum source for procedure	Almost identical. The one small difference is the predicate device requires a foot control pedal to connect to an electrosurgical generator The application device can be hand or foot controlled. Otherwise, identical.
Use only in Conductive Media	The electrode is to be activated only when immersed in a conductive media such as standard saline solution	Same	Same	Identical

Feature	**Application Device:** *Eblator Device*	**Predicate Device:** Bovie Disposable Bipolar Ablator (K152777)	**Predicate Device:** Bovie Disposable Bipolar Ablator (K161558)	**Pertinence of Feature to Consideration of Substantial Equivalence.**
Design –Mechanism				
Main Component	insulated handle, active electrode, aspirating tube, return connector, footswitch connector (optional)	insulated handle, active electrode, aspirating tube, return connector, footswitch connector	insulated handle, active electrode, aspirating tube, return connector, footswitch connector	Similar
Handle Width	1'' (25.2 mm)	0.82'' (20.8 mm)	0.82'' (20.8 mm)	Similar
Device Length (without cable and tube)	13.5'' (343 mm)	11.85'' (301.0 mm)	11.85'' (301.0 mm)	Similar
Cable Length from the Handle	12 feet	10 feet	10 feet	Functionally identical
User interface	Handswitch integrated in the handle or Footswitch	Footswitch	Footswitch	Functionally identical
Aspirating and Non-Aspirating Models	Yes	Yes	Yes	Identical
Outer Diameter at end of the ceramic insulator	4.0 mm	4.0 mm	4.0 mm (90° Ablator)	Identical
Electrode Face Angle	50, 90 degrees	50 degrees	55, 60, and 90 degrees	Identical to a subset of the predicates
Working Length	160 mm	Same	Same	Identical
Other Attributes				
Single Use or Reusable	Single use	Same	Same	Identical
Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Identical
Standard Met	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2 FDA RF Guidance	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2	Almost identical, application device is in conformance with latest version of the standards

F. Summary of Supporting Data

Performance testing was completed to demonstrate substantial equivalence of the application device to the predicates. The application device was subjected to the following verification and validation tests, as applicable:

Mechanical testing

Mechanical verification testing was conducted for the proposed device to ensure compliance with mechanical requirements of IEC-60601-1, Ed 3.2, 2005 + AM1:2012 + AM2:2020; IEC 60601-2-2, Ed 6.0: 2017, and E Surgical self-enforced requirements.

- Monopolar and Return Plug Insertion/Extraction Force
- Snap Fit Strength
- Weld Integrity Test
- Probe Flexural Test
- Probe Axial Pull Force

Electrical testing

Electrical verification testing was conducted for the relevant components of the application device to ensure compliance with current electrical standard requirements described above.

Electromagnetic compatibility

Electromagnetic compatibility (EMC) testing has been completed for the applicable components of the proposed device. The results demonstrated compliance of the application device to current IEC 60601-1-2, Ed 4.1: 2017 + AM1:2020 standard requirements.

Biocompatibility

Biocompatibility verification was performed in accordance with requirements of ISO 10993-1 and FDA's modified ISO guidelines.

Bench-top validation testing

Standard Tests:

- Cable Dynamic Strain Relief
- Cable Static Strain Relief
- Anchorage Test
- Fluid Ingress Test
- HF Leakage Current
- HF Dielectric Strength Test
- Mains Frequency Dielectric Strength Test
- Housing Temperature Verification

Non-Standard Tests:

- Visual Inspection
- Function Test
- Activation Force

- Continuity & Activation Switch Resistance
- Activation Over Time
- Aspiration Tube Dynamic Strain Relief
- Aspiration Tube Static Strain Relief
- Distal Fluid Ingress Test
- Active Electrode to Inner Tube Torque Test
- Fluid Leak Test
- Activation Thermal Performance Test

Packaging Tests:

- Burst Test
- Seal Strength Test
- Bubble Leak Test
- Dye Leak Test

An accelerated aging evaluation test demonstrated compliance of the Eblator Device to meet the defined product specifications after 2 year storage.

The thermal effects of the Eblator Device on *ex vivo* tissue was evaluated by measuring the size of the thermal damage zone caused by the Eblator Device compared to the size of thermal damage zone caused by the predicate device under the same generator mode and power settings. Validation was conducted in three different tissues (porcine muscle, liver, and kidney). In all cases there was no clinical difference between the thermal damage caused by the Eblator Device and the predicate.

All test requirements were met as specified by applicable standards and the test protocols.

The application Eblator Device was tested and found to be in compliance with the pertinent portions of the following standards:

Standards Body & #	Standard Name	Standard Version
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	2005 + AM1:2012 +AM2:2020
IEC 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests	2017 + AM1:2020
IEC 60601-2-2	Medical electrical equipment –Part 2-2: Particular requirements for the safety of high frequency surgical equipment	2017
ISO 10993-1	Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process.	2018
ISO 11135	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices	2014 + AM1: 2018

Standards Body & #	Standard Name	Standard Version
ISO 11607-1	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems;	2019
ISO 11607-2	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes	2019
ASTM F1980	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	2016

In addition, the Eblator Device was fully tested and found to be in compliance with the FDA guideline *Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery: Guidance for Industry and Food and Drug Administration Staff* (9 March 2020).

G. Conclusion

After comparing the indications for use, technology and design of the Eblator Device and the predicate devices, along with all electrical safety (including IEC 60601-1: 2005 + AM1:2012; IEC 60601-1-2: 2014; IEC 60601-2-2: 2017) and performance testing (including the thermal effects of the devices on three different tissues), and in accordance with the FDA's guidelines and FDA-recognized consensus standards for such devices, E Surgical concludes that the Eblator Device is substantially equivalent to the predicate Bovie Disposable Bipolar Ablators (K152777, K161558).