New Deantronics Taiwan Ltd.
% Coombs Craig
President
Coombs Medical Device Consulting, Inc.
427 14th Ave
San Francisco, California 94118

October 1, 2025

Re: K251899
Trade/Device Name: E Blator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 2, 2025
Received: September 2, 2025

Dear Coombs Craig:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2025.10.01 14:46:58 -04'00'

Colin Kejing Chen, Ph.D.
Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251899

Please provide the device trade name(s).

E Blator

Please provide your Indications for Use below.

The E Blator 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.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary for K251899

A. Device Information:

Category	**Comments**
Sponsor:	New Deantronics Taiwan Ltd. 12F. No.51, Sec. 4, Zhongyang Rd., Tucheng Dist., New Taipei City, 236 Taiwan
Correspondent Contact Information:	Mr. Craig Coombs President Coombs Medical Device Consulting, Inc. 427 14 th Ave, San Francisco, CA, 94118 Tel: 650-380-2474 Email: craigJcoombs@gmail.com
Common Name	Electrosurgical accessory
Classification Number	21 CFR 878.4400
Classification & Product Code	Class II, GEI
Proprietary Name	E Blator

Predicate Device Information:

Predicate Device	Eblator Device
Manufacturer	E Surgical, LLC
Common Name	Electrosurgical Ablator
Premarket Notification #	K231126
Classification	21 CFR 878.4400
Classification & Product Code	Class 2, GEI

Reference Device 1:

Reference Device	Bovie Disposable Bipolar Ablator
Manufacturer	Bovie Medical Corporation
Common Name	Electrosurgical Generator Accessory
Premarket Notification #	K161558
Classification	21 CFR 878.4400
Classification & Product Code	Class 2, GEI

Reference Device 2:

Reference Device	Arthrex Synergy RF System
Manufacturer	Arthrex, Inc.
Common Name	Electrosurgical, Cutting & Coagulation device and accessories
Premarket Notification #	K161581
Classification	21 CFR 878.4400
Classification & Product Code	Class 2, GEI

Reference Device 3:

Reference Device	Arthrex OPES Electrodes and Accessories Ablator
Manufacturer	Arthrex, Inc
Common Name	High Frequency Devices and Accessories
Premarket Notification #	K023986
Classification	21 CFR 878.4400
Classification & Product Code	Class 2, GEI

B. Date Summary Prepared

1 October 2025

C. Description of Device

The device is equipped with a patented stainless steel electrode tip encased in a thermal insulator. When used in combination with a compatible electrosurgical generator, the device provides radio frequency (RF) energy for cutting, vaporizing, and coagulating soft tissue. The device enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect with handswitch control, said current then returns back to the electrosurgical unit through the return electrode and connector. This provides the capability for the surgeon to balance tissue dissection and hemostatic effects as needed during a given surgical case. For aspirating models, when coupled with a vacuum system, the surgical field can be cleared of undesirable debris simultaneously by using the aspiration port located at the bottom of the face of the electrode. Removing this debris can facilitate the surgeon's visualization of the surgical field.

D. Indications for Use

The E Blator 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

This section presents the justification for the substantial equivalence between the subject device, the New Deantronics E Blator, and the predicate and reference devices, including the E Surgical Eblator (K231126, predicate), Bovie Disposable Bipolar Ablator (K161558, reference 1), Arthrex Synergy RF System (K161581, reference 2), and Arthrex OPES Electrodes and Accessories Ablator (K023986, reference 3).

The tabular comparison of E Blator is thus split up into three tables in accordance with the different electrode tip configurations.

(I) Classic Tip

Feature	**Application Device** New Deantronics E Blator	**Predicate Device** E Surgical Eblator (K231126)	**Reference Device 1** Bovie Disposable Bipolar Ablator (K161558)	**Pertinence of Feature to Consideration of Substantial Equivalence**
Indications for Use	The E Blator 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.	The E Surgical Eblator device is intended for general arthroscopic applications, which includes cutting, vaporization, and coagulation. This device is intended to be used in conjunction with a general purpose electrosurgical generator active lead and 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.	Identical to predicate and reference 1, except for the name of the device.
Product Code	GEI	GEI	GEI	Identical

Feature	Application Device New Deantronics E Blator	Predicate Device E Surgical Eblator (K231126)	Reference Device 1 Bovie Disposable Bipolar Ablator (K161558)	Pertinence of Feature to Consideration of Substantial Equivalence
Device Category	**Classic Tip** RB4050A-01 (4.0mm), RB4050-01 (4.0mm), RB4090A-01 (4.0mm), RB4090-01 (4.0mm), RB4090A-02 (4.0mm), RB4090-02 (4.0mm), RB4050A-02 (4.0mm), RB4050-02 (4.0mm), RB3455-01 (3.4mm), RB3490-01 (3.4mm), RB2790-01 (2.7mm), RB2760-01 (2.7mm), RB2790-00 (2.7mm), RB2760-00 (2.7mm)	**Classic Tip** RB4050A-01 (4.0mm), RB4050-01 (4.0mm), RB4090A-01 (4.0mm), RB4090-01 (4.0mm)	**Classic Tip** BA2455NA (2.4mm), BA1860NA (1.8mm)	The application device presents a subset of models (Classic Tip) that are the same as the predicate and the reference 1 devices.
Technology				
Energy Use	Radiofrequency electrical energy	Same	Same	Identical to both
Power output	From monopolar port	Same	Same	Identical to both
Operation Mode	Bipolar	Same	Same	Identical to both
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 to both
Equipment Mated	General purpose electrosurgical	General purpose electrosurgical	Standard electrosurgical generator	Identical to the predicate

Feature	**Application Device** New Deantronics E Blator	**Predicate Device** E Surgical Eblator (K231126)	**Reference Device 1** Bovie Disposable Bipolar Ablator (K161558)	**Pertinence of Feature to Consideration of Substantial Equivalence**
	generator with standard return electrode connection. Compatible foot switch controller is optional. **Aspiration**: Adequate vacuum source for procedure (Applicable to these models: RB4050A-01, RB4090A-01, RB4090A-02, RB4050A-02)	generator with standard return electrode connection. Compatible foot switch controller is optional. **Aspiration**: Adequate vacuum source for procedure (Applicable to these models: RB4050A-01, RB4090A-01)	with standard return electrode connection. Compatible foot switch controller is required. **Aspiration:** Adequate vacuum source for procedure	
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 to both
Design –Mechanism				
Main Component	Insulated handle, Active electrode, Aspirating tube, Cable with ESU plug and return connector	Insulated handle, Active electrode, Aspirating tube Cable with ESU plug and return connector	Insulated handle, Active electrode, Aspirating tube, Return connector Footswitch connector	Identical to the predicate.
Handle Width	1'' (25.2 mm)	1'' (25.2 mm)	0.82'' (20.8 mm)	Identical to the predicate.
Device Length (without cable and tube)	9.76'' (248 mm), 13.5'' (343 mm), 14.49'' (368 mm)	13.5'' (343 mm)	11.85'' (301.0 mm)	Functionally identical to both
Cable Length	12 feet	12 feet	10 feet	Identical to the predicate
User interface	Handswitch integrated in the handle or Footswitch	Handswitch integrated in the handle or Footswitch	Footswitch	Identical to the predicate

Feature	**Application Device** New Deantronics E Blator	**Predicate Device** E Surgical Eblator (K231126)	**Reference Device 1** Bovie Disposable Bipolar Ablator (K161558)	**Pertinence of Feature to Consideration of Substantial Equivalence**
Aspirating Feature	***Classic Tip:*** Aspirating or non-aspirating	Aspirating or non-aspirating	Aspirating or non-aspirating	Identical to both
Shaft Diameter	3.6 mm, 4.4 mm	4.4 mm	3.6 mm, 4.4mm	Functionally identical to both. Identical to the reference 1
Outer Diameter at end of the ceramic insulator	***Classic Tip*** 2.7mm, 3.4mm, 4.0mm	***Classic Tip*** 4.0mm	***Classic Tip*** 2.7mm, 3.4mm	Functionally identical to both
Electrode Angle	***Classic Tip:*** 50°, 60°, 90°	***Classic Tip:*** 50°, 90°	***Classic Tip:*** 55°,60°	Functionally identical to both
Working Length	65mm, 160mm, 185mm	155 mm	160 mm	Functionally identical to both as demonstrated in Thermal Testing
Design- Electrical Feature				
Maximum Allowable Voltage	1800 V_p	1800 V_p	1800 V_p	Identical to both
Electrical Safety	Withstand 2160 V_p (120% of 1800V_p) for High Frequency breakdown Withstand 2800 V_p (1000+1800V_p) at Main Frequency (60Hz) breakdown	Withstand 2160 V_p (120% of 1800V_p) for High Frequency breakdown Withstand 2800 V_p (1000+1800V_p) at Main Frequency (60Hz) breakdown	Follow IEC 60601-2-2 requirement	Identical to the predicate
Design- Material				
Electrode	SUS 304	Same	Same	Identical to both
Insulator	Ceramic	Same	Same	Identical to both
Aspiration Tube	PVC	PVC	Tygon™	Identical to the predicate
Aspiration Adaptor	ABS	Same	Same	Identical to both

Feature	**Application Device** New Deantronics E Blator	**Predicate Device** E Surgical Eblator (K231126)	**Reference Device 1** Bovie Disposable Bipolar Ablator (K161558)	**Pertinence of Feature to Consideration of Substantial Equivalence**
Heat Shrink Tube	PVDF, POF	Same	Same	Identical to both
Inner Tube	SUS 304	Same	Same	Identical to both
Outer Tube	SUS 304	Same	Same	Identical to both
Adhesive	Epoxy	Same	Same	Identical to both
Other Attributes				
Single Use or Reusable	Single use	Same	Same	Identical to both
Sterilization	Ethylene Oxide	Same	Same	Identical to both
Standards 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 FDA RF Guidance	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2 FDA RF Guidance	Identical to both

(II) Hook

Feature	Application Device New Deantronics E Blator	Predicate Device E Surgical Eblator (K231126)	Reference Device 2 Arthrex Synergy RF System (K161581)	Pertinence of Feature to Consideration of Substantial Equivalence
Indications for Use	The E Blator 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.	The E Surgical Eblator device is intended for general arthroscopic applications, which includes cutting, vaporization, and coagulation. This device is intended to be used in conjunction with a general purpose electrosurgical generator active lead and standard return lead connection. The device is only operable when activated in an appropriate conductive media, such as a standard saline solution.	The RF Probe are accessories to the Synergy RF Console and are intended for use as a complete system in the resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels and tissue in arthroscopic and orthopedic procedures. Specifically, the RF probes, Synergy RF Console and their accessories are used for arthroscopic surgery of the shoulder, wrist, hand, elbow, hip, knee, foot and ankle.	Identical to the predicate, except for the name of the device. The applications of the E Blator are clinically equivalent (cutting, vaporization, coagulation) to that of the reference devices.
Product Code	GEI	GEI	GEI	Identical to both
Device Category	**Hook** RB0700-21 (0.75 mm, 0°)	**Classic Tip** RB4050A-01 (4.0mm, 50°), RB4050-01 (4.0mm, 50°), RB4090A-01(4.0mm, 90°), RB4090-01 (4.0mm, 90°)	**Hook** AR-9825 (0.75 mm, 0°)	The application device includes Hook-type model that is identical to Reference Device 2.
Technology				
Energy Use	Radiofrequency electrical energy	Same	Same	Identical to both
Power Output	From monopolar port	Same	Same	Identical to both
Operation Mode	Bipolar	Same	Same	Identical to both
Operation Principle	Use RF power to generate arcing through bubbles formed between an active electrode and tissue with the	Same	Same	Identical to both

Feature	Application Device New Deantronics E Blator	Predicate Device E Surgical Eblator (K231126)	Reference Device 2 Arthrex Synergy RF System (K161581)	Pertinence of Feature to Consideration of Substantial Equivalence
	tissue being vaporized by the arcing.			
Equipment Mated	General purpose electrosurgical generator with standard return electrode connection. Compatible foot switch controller is optional.	General purpose electrosurgical generator with standard return electrode connection. Compatible foot switch controller is optional. **Aspiration**: Adequate vacuum source for procedure (Applicable to these models: RB4050A-01, RB4090A-01)	Specific electrosurgical gnenerator (SynergyRF™ Bipolar Ablation System)	Identical to the predicate
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 to both
Design –Mechanism				
Main Component	Insulated handle, Active electrode, Aspirating tube, Cable with ESU plug and return connector	Insulated handle, Active electrode, Aspirating tube Cable with ESU plug and return connector	Insulated handle, Active electrode, Cable with integrated plug	Identical to the predicate.
Handle Width	1'' (25.2 mm)	1'' (25.2 mm)	0.95" (24 mm)	Identical to the predicate.
Device Length (without cable and tube)	13.5'' (343 mm)	13.5'' (343 mm)	12.6" (320 mm)	Functionally identical to both
Cable Length	12 feet	12 feet	10 feet	Identical to the predicate
User interface	Handswitch integrated in the handle or Footswitch	Handswitch integrated in the handle or Footswitch	Handswitch integrated in the handle or Footswitch	Identical to both

Feature	**Application Device** New Deantronics E Blator	**Predicate Device** E Surgical Eblator (K231126)	**Reference Device 2** Arthrex Synergy RF System (K161581)	**Pertinence of Feature to Consideration of Substantial Equivalence**
Aspirating Feature	***Hook:*** Non-Aspirating	Aspirating or Non-Aspirating	Non-Aspirating	Identical to both
Shaft Diameter	4.4 mm	4.4 mm	4.15 mm	Identical to the predicate
Outer Diameter at end of the ceramic insulator	***Hook:*** 0.75 mm	***Classic Tip:*** 4.0 mm	***Hook:*** 0.75 mm	Identical to the Ref #2. Functionally identical to both
Electrode Angle	***Hook:*** 0°	***Classic Tip:*** 50°, 90°	***Hook:*** 0°	Identical to the reference 2 device. Functionally identical to both
Working Length	160 mm	Same	Same	Identical to both
Design- Electrical Feature				
Maximum Allowable Voltage	1800 V_p	1800 V_p	550V (round)	Identical to the predicate
Electrical Safety	Withstand 2160 V_p (120% of 1800V_p) for High Frequency breakdown Withstand 2800 V_p (1000+1800V_p) at Main Frequency (60Hz) breakdown	Withstand 2160 V_p (120% of 1800V_p) for High Frequency breakdown Withstand 2800 V_p (1000+1800V_p) at Main Frequency (60Hz) breakdown	Follow IEC 60601-2-2 requirement	Identical to the predicate
Design- Material				
Electrode	SUS 304	Same	Same	Identical to the predicate
Insulator	Ceramic	Same	Same	Identical to the predicate
Aspiration Tube	(N/A)	(N/A)	(N/A)	Identical to both. The hook electrode model does not include an aspiration tube is identical to the non-aspirating versions of the predicate

Feature	**Application Device** New Deantronics E Blator	**Predicate Device** E Surgical Eblator (K231126)	**Reference Device 2** Arthrex Synergy RF System (K161581)	**Pertinence of Feature to Consideration of Substantial Equivalence**
Aspiration Adaptor	(N/A)	(N/A)	(N/A)	Identical to both. The hook electrode model does not include an adaptor is identical to the non-aspirating versions of the predicate device.
Heat Shrink Tube	PVDF, POF	Same	Same	Identical to both
Inner Tube	SUS 304	Same	Same	Identical to both
Outer Tube	SUS 304	Same	Same	Identical to both
Adhesive	Epoxy	Same	Same	Identical to both
Other Attributes				
Single Use or Reusable	Single use	Same	Same	Identical to both
Sterilization	Ethylene Oxide	Same	Same	Identical to both
Standards 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 FDA RF Guidance	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2 FDA RF Guidance	Identical to both

(III) Ball

Feature	**Application Device** New Deantronics E Blator	**Predicate Device** E Surgical Eblator (K231126)	**Reference Device 3** Arthrex OPES Electrodes and Accessories Ablator (K023986)	**Pertinence of Feature to Consideration of Substantial Equivalence.**
Indications for Use	The E Blator 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.	The E Surgical Eblator device is intended for general arthroscopic applications, which includes cutting, vaporization, and coagulation. This device is intended to be used in conjunction with a general purpose electrosurgical generator active lead and standard return lead connection. The device is only operable when activated in an appropriate conductive media, such as a standard saline solution.	The Arthrex electrosurgical cutting and coagulation devices and accessories are monopolar in structure, allowing for use in a range of surgical procedures. The Arthrex electrosurgical ablation devices and accessories are intended for use in resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels and tissue in general, arthroscopic, and orthopedic procedures. Specifically, these devices and their accessories will be used for general surgeries, and open and arthroscopic surgery of the shoulder, wrist, hand, elbow, hip, knee, and ankle.	Identical to the predicate, except for the name of the device. The applications of the E Blator are clinically equivalent (cutting, vaporization, coagulation) to that of the reference devices.
Product Code	GEI	GEI	GEI	Identical to both

Feature	**Application Device** New Deantronics E Blator	**Predicate Device** E Surgical Eblator (K231126)	**Reference Device 3** Arthrex OPES Electrodes and Accessories Ablator (K023986)	**Pertinence of Feature to Consideration of Substantial Equivalence.**
Device Category	**Ball** RB2000-11 (2.0 mm, 0°), RB2040-11 (2.0 mm, 40°)	**Classic Tip** RB4050A-01 (4.0mm, 50°), RB4050-01 (4.0mm, 50°), RB4090A-01(4.0mm, 90°), RB4090-01 (4.0mm, 90°)	**Ball** AR-9808SJ-45 (0.8 mm, 45°), AR-9808SJ (0.8 mm, 0°)	The application device presents a subset of models (Ball) that are present in the reference 3 device.
Technology				
Energy Use	Radiofrequency electrical energy	Same	Same	Identical to both
Power output	From monopolar port	Same	Same	Identical to both
Operation Mode	Bipolar	Bipolar	Monopolar	Identical to the predicate. Technically identical to the reference 3 device
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 to both
Equipment Mated	General purpose electrosurgical generator with standard return electrode connection. Compatible foot switch controller is optional.	General purpose electrosurgical generator with standard return electrode connection. Compatible foot switch controller is optional. **Aspiration**: Adequate vacuum source for procedure (Applicable to these models: RB4050A-01, RB4090A-01)	General purpose electrosurgical generator with standard return electrode connection	Identical to both

Feature	**Application Device** New Deantronics E Blator	**Predicate Device** E Surgical Eblator (K231126)	**Reference Device 3** Arthrex OPES Electrodes and Accessories Ablator (K023986)	**Pertinence of Feature to Consideration of Substantial Equivalence.**
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 to both
Design –Mechanism				
Main Component	Insulated handle, Active electrode, Aspirating tube, Cable with ESU plug and return connector	Insulated handle, Active electrode, Aspirating tube Cable with ESU plug and return connector	Insulated handle, Active electrode Cable with ESU plug	Identical to the predicate.
Handle Width	1'' (25.2 mm)	1'' (25.2 mm)	0.95" (24 mm)	Identical to the predicate.
Device Length (without cable and tube)	13.5'' (343 mm)	13.5'' (343 mm)	8.86" (225 mm)	Functionally identical to both
Cable Length	12 feet	12 feet	10 feet	Identical to the predicate
User interface	Handswitch integrated in the handle or Footswitch	Handswitch integrated in the handle or Footswitch	Handswitch integrated in the handle or Footswitch	Identical to both
Aspirating Feature	***Ball:*** Non-Aspirating	Aspirating or non-aspirating	Non-Aspirating	Identical to both
Shaft Diameter	4.4 mm	4.4 mm	4.15 mm	Identical to the predicate
Outer Diameter at end of the ceramic insulator	***Ball:*** 2.0 mm	***Classic Tip:*** 4.0 mm	***Ball:*** 0.8 mm	Identical geometry to the reference 3 device. Functionally identical to predicate in Thermal Testing.

Feature	**Application Device** New Deantronics E Blator	**Predicate Device** E Surgical Eblator (K231126)	**Reference Device 3** Arthrex OPES Electrodes and Accessories Ablator (K023986)	**Pertinence of Feature to Consideration of Substantial Equivalence.**
Electrode Angle	***Ball:*** 40°, 0°	***Classic Tip:*** 50°, 90°	***Ball:*** 45°, 0°	Functionally identical to both
Working Length	160 mm	160 mm	65 mm	Identical to the predicate
Design- Electrical Feature				
Maximum Allowable Voltage	1800 V_p	1800 V_p	6750$_p$	Identical to the predicate
Electrical Safety	Withstand 2160 V_p (120% of 1800V_p) for High Frequency breakdown Withstand 2800 V_p (1000+1800V_p) at Main Frequency (60Hz) breakdown	Withstand 2160 V_p (120% of 1800V_p) for High Frequency breakdown Withstand 2800 V_p (1000+1800V_p) at Main Frequency (60Hz) breakdown	Follow IEC 60601-2-2 requirement	Identical to the predicate
Design- Material				
Electrode	SUS 304	Same	Same	Identical to both
Insulator	Heatshrink	Ceramic	Heatshrink	Functionally identical to both
Aspiration Tube	(N/A)	(N/A)	(N/A)	Identical to both. The ball electrode models do not include an aspiration tube are identical to the non-aspirating versions of the predicate device.
Aspiration Adaptor	(N/A)	(N/A)	(N/A)	Identical to both. The ball electrode models do not include an adaptor and are identical to the non-aspirating versions of

Feature	Application Device New Deantronics E Blator	Predicate Device E Surgical Eblator (K231126)	Reference Device 3 Arthrex OPES Electrodes and Accessories Ablator (K023986)	Pertinence of Feature to Consideration of Substantial Equivalence.
				the predicate device.
Heat Shrink Tube	PVDF, POF	Same	Same	Identical to both
Inner Tube	SUS 304	Same	Same	Identical to both
Outer Tube	SUS 304	Same	Same	Identical to both
Adhesive	Epoxy	Same	Same	Identical to both
Other Attributes				
Single Use or Reusable	Single use	Same	Same	Identical to both
Sterilization	Ethylene Oxide	Same	Same	Identical to both
Standards 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 FDA RF Guidance	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2 FDA RF Guidance	Identical to both

F. Summary of Supporting Data

The E Blator was tested and found to be in compliance with the pertinent portions of the following standards:

Standards	Title	Version
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	2005 + AMD1:2012 +AMD2:2020
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	2014 +AMD1:2020
IEC 60601-2-2	Medical electrical equipment –Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	2017 + AMD1:2023
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 + AMD1: 2018
ISO 11607-1	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems	2019 + AMD1:2023
ISO 11607-2	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes	2019+ AMD1:2023

In addition, the E Blator was fully tested and 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 E Blator, along with all electrical safety and performance testing, in accordance with the FDA's guidelines and FDA-recognized consensus standards for electrical safety, New Deantronics concludes that the E Blator is substantially equivalent to the predicate and reference devices.