March 20, 2024

Excelsior
% Andrea Steiner
Regulatory Affairs Consultant
Medlogics International LLC
12245 NW 48th Drive
Coral Springs, Florida 33076

Re: K233002
Trade/Device Name: Beed 2,5, Beed 3,8
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 16, 2024
Received: February 16, 2024

Dear Andrea Steiner:

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.

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2024.03.20 08:50:15 -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)*

Device Name
BEED 3,8
BEED 2,5

Indications for Use *(Describe)*
The BEED 3,8 and BEED 2,5 device are used for electrosurgical cutting and coagulation through tissues, or within tissue planes while maintaining hemostasis.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(k) Summary

Applicant Name	Excelsior Resources, LLC 3011 NE 44th Street Fort Lauderdale, FL 33308
Contact Person	Andrea Dwyer Steiner, MS, RAC MedLogics International, LLC Chief Regulatory Affairs Consultant
Date Summary Prepared:	March 18, 2024
Device Trade Name	BEED-2,5 BEED-3,8
Common Device Name	Electrosurgical, Cutting & Coagulation & Accessories
Device Classification	Class II
Review Panel	General & Plastic Surgery
Product Code	GEI
Regulation Number	21 CFR Section 878.4400
Predicate Device	K960255 - Epitome Ceramic Blade Electrode

Device Description

The BEED device is available in two configurations as BEED-2,5 or BEED-3,8 and is a monopolar, Bead-Enhanced Electrosurgical Dissector (BEED) that dissects and separates tissue planes using both forward and backward strokes. Distal facing beads and lysing segments enable forward dissection. The proximal facing bead and lysing segment allow for rearward dissection.

BEED operates when connected to a compatible electrosurgical unit (ESU) via a universal 4mm monopolar connector cable, and a neutral electrode that shall be used with the ESU. The compatible ESU supplies current and voltage to the device and is typically controlled via a footswitch. The power supplied to the BEED device can range from 20- 50 Watts, depending on user preference.

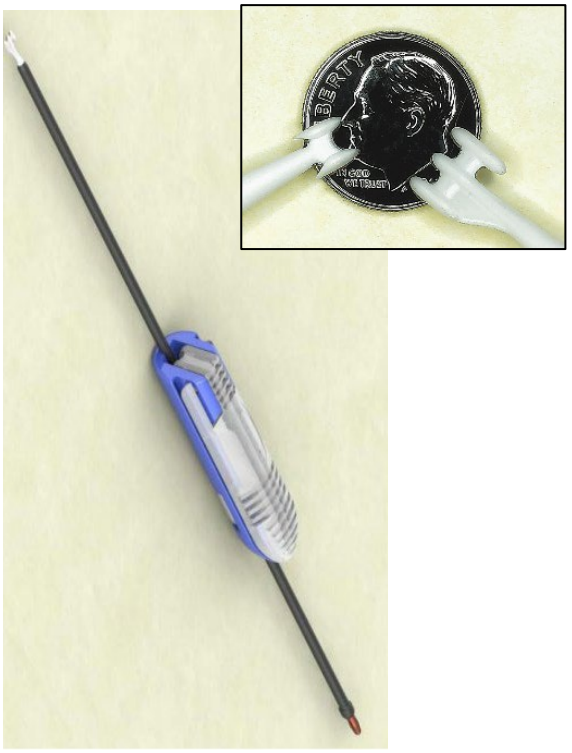
The BEED-2,5 model consists of two bead-like structures, two RF electrified (monopolar) cutting edges protectively recessed between two non-conductive ceramic protrusions on the distal end and measures 5mm in width and may be preferred for smaller cuts. Whereas the BEED-3,8 model is larger and consists of three bead-like structures and three RF electrified (monopolar) cutting edges protectively recessed within three non-conductive ceramic protrusions on the distal end and measures 8mm in width.

Each BEED model is provided with a clamp-on, adjustable plastic handle that can lock along various lengths of the shaft.

Indications for Use

The BEED devices are used for electrosurgical cutting and coagulation through tissues, or within tissue planes, while maintaining hemostasis.

Predicate Comparison

Description	Utah Medical Products Inc. Ceramic Blade Electrode (CBE) K960255 (Predicate)	BEED (Subject Device) 510(k) TBD
510(k)	**K960255**	**TBD**
Device Image		
Device Description	Ceramic Blade Electrodes (CBE) device consists of a single tip mounted on a shaft that plugs into a standard electrosurgical pencil which plugs into an ESG.	BEED consists of a tip mounted on a shaft with a proximal metal post that plugs into a ESG connector cable. A clamping handle adjusts along the length of shaft.
Indications for Use	The Utah Medical Products Inc. Ceramic Blade Electrodes (CBE) are intended for use in virtually every surgical discipline where flat, paddle-type electrosurgical blades are used for making straight cuts through tissue. The CBE-2XX blades are intended for use in procedures that require precise cuts where only light or no hemostasis is desired. The CBE-1XX blades are intended for use in procedures where a greater level of hemostasis is desired. When an electrosurgical generator blend mode is used for cutting with the CBE-	The BEED-3,8 and BEED-2,5 devices are used for electrosurgical cutting and coagulation through tissues, or within tissue planes, while maintaining hemostasis.

<table>
<tr><td></td><td>1XX blades, cauterization of the wound will occur while the cut is being made.</td><td></td></tr>
<tr><td>Intended Use</td><td>Cut tissue while maintaining hemostasis</td><td>Same</td></tr>
<tr><td>Product Code</td><td>GEI</td><td>Same</td></tr>
<tr><td>OTC or Prescription</td><td>Prescription Use Only</td><td>Same</td></tr>
<tr><td>Energy Source/Type</td><td>Radiofrequency Electrosurgical Generator in monopolar mode</td><td>Same</td></tr>
<tr><td>Tip Description / Electrode Exposure</td><td>Exposed fine wire element surrounding the periphery of a flat, non-conductive, blade-shaped, ceramic core.</td><td>BEED 2,5 contains1 distal electrode segment while BEED 3,8 contains 2 distal electrode segments. The distal electrode segments are recessed/shielded between 2 bead-like structures and 1 proximal facing electrode segment is recessed/shielded between 1 bead-like structure and the ceramic shaft.</td></tr>
<tr><td>Mode of Operation</td><td>The CBE electrode is oriented so that the distal-most end of the CBE wire electrode cuts and/or coagulates tissue.

Using monopolar RF energy, the device cuts through and coagulates tissues.</td><td>BEED electrodes separate tissue planes during surgery through the use of both forward and backward strokes.

Using monopolar RF energy, the device cuts through and coagulates tissues.</td></tr>
<tr><td>Device Activation Mode</td><td>Finger switch button activation with standard ESG pencil or foot switch activation with foot-activated ESG pencil.

Yellow button delivers CUT or Blend energy; blue button delivers COAG energy.</td><td>Foot Switch activates ESU/ ESG to power connector cable leading to BEED device.

Yellow button delivers CUT or Blend energy; blue button delivers COAG energy.</td></tr>
<tr><td>Tip Component Materials</td><td>Yitria Partially-Stabilized Zirconia Ceramic (nonconductive, blade-shaped ceramic core)
302 pr 304 Stainless Steel (electrode wire)</td><td>Yitria Partially-Stabilized Zirconia Ceramic (nonconductive guard protectively sequesters electrode segments)
Stainless Steel 316 (electrode and its segments)</td></tr>
<tr><td>Tip Dimensions</td><td>
<table>
<tr><th></th><th>CBE-100</th><th>CBE-150</th></tr>
<tr><td>Blade Length</td><td>17.8mm</td><td>17.8mm</td></tr>
<tr><td>Blade Width</td><td>4.3mm</td><td>4.3mm</td></tr>
<tr><td>Blade Thickness</td><td>0.58mm</td><td>0.58mm</td></tr>
<tr><td>Electrode Length Total Exposed</td><td>39mm</td><td>39mm</td></tr>
</table>
</td><td>
<table>
<tr><th></th><th>BEED 2,5</th><th>Beed 3,8</th></tr>
<tr><td>Tip Length (ceramic)</td><td>17.2mm</td><td>17.2mm</td></tr>
<tr><td>Tip Width</td><td>5.27mm</td><td>7.9mm</td></tr>
<tr><td>Tip Thickness</td><td>2.65mm</td><td>2.76mm</td></tr>
<tr><td>Electrode Length Total Recessed</td><td>3mm</td><td>5mm</td></tr>
</table>
</td></tr>
</table>

Generator Compatibility	Any generator that accepts (A) 3-prong accessory plugs (1 carrying RF source, other 2 signal cut or coag modes) or (B) single-lead foot-pedal-activated connector cords	Any generator that accepts a universal 4mm monopolar connector cable (foot pedal activated)
Electrical Safety/ EMC compliance	IEC 60601-1-2 IEC 60601-2-2	IEC 60601 compliant
Maximum Power	150 Watts	50 Watts
Sterilization Method	Ethylene Oxide	Gamma

Performance Data

The FDA guidance document, "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery" (2020) was considered in evaluating BEED's electrical and functional capabilities. The device was evaluated through the following non-clinical performance tests

Design Verification

The BEED device was subjected to a series of mechanical and functional tests to evaluate its safety and efficacy. The design verification evaluation confirmed that the design inputs met the design output requirements.

Sterility

The BEED device is supplied sterile and conforms to a Sterility Assurance Level (SAL) of 10^{-6}. BEED meets the sterilization requirements of ISO 11137-2:2013 (R) 2019.

EMC and Electrical Safety Testing

The BEED device was evaluated for electrical and electromagnetic safety testing in accordance with IEC 60601-2-2 and IEC 60601-1-2 respectively and met all applicable acceptance criteria.

Thermal Safety Testing

The thermal safety of the device was successfully evaluated in line with FDA guidance, "*Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery*", issued March 9, 2020.

Biocompatibility Testing

BEED is classified as an external communicating device that contacts tissue/ bone/dentin for a limited exposure (<24 hours). The device was evaluated in accordance ISO 10993-1 and FDA Guidance, “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process” and met all acceptance criteria.

Design & User Validation

The BEED device was evaluated during a user validation to confirm that the IFU and packaging provide the user with appropriate instructions and that the device meets its intended use during simulated use.

Conclusion

The successful completion of all testing verify that the BEED devices do not raise new or different risks from that of the Utah Medical CBE predicate and therefore can be considered substantially equivalent based on the similarity of intended use, technological characteristics, materials of construction and principles of operation,