March 2, 2020

Covidien, LLC
Juma Hoshino
Regulatory Affairs Manager
5920 Longbow Drive
Boulder, Colorado 80301

Re: K193356
Trade/Device Name: BiZact Tonsillectomy Device Advanced Bipolar Tissue Sealer/Divider
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 3, 2019
Received: December 4, 2019

Dear Juma Hoshino:

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,

for Michael J. Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193356

Device Name
BiZact™ Tonsillectomy Device Advanced Bipolar Tissue Sealer/Divider

Indications for Use *(Describe)*
The BiZact device is a bipolar instrument intended for use in open surgical procedures where ligation and division of vessels, tissue bundles and lymphatics is desired. The tissue fusion of the device can be used on vessels (arteries and veins) and lymphatics up to an including 3 mm diameter. The BiZact device is indicated for use in open general surgical procedures.

It's also indicated for adult, children and adolescent ENT procedures (3 years of age and above), including tonsillectomy, for the ligation and division of vessels, tissue bundles and lymphatics 2-3 mm away from unintended thermally sensitive structures.

The BiZact device has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use for these procedures.

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.

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COVIDIEN

510(k) Summary

Date summary prepared: March 2, 2020

510(k) Submitter/Holder
Covidien llc
5920 Longbow Drive
Boulder, CO 80301

Contact:
Juma Hoshino
Regulatory Affairs Manager
Telephone: 303-530-6541
Email: juma.hoshino@medtronic.com

Name of Device

Trade Name:	BiZact™ Tonsillectomy Device Advanced Bipolar Tissue Sealer/Divider
Catalog Number:	BZ4212A
Common Name:	Bipolar Vessel Sealing Device
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR §878.4400, Class II, GEI)

Predicate Device

Trade Name:	BiZact™ Tonsillectomy Device Advanced Bipolar Tissue Sealer/Divider
Catalog Number:	BZ4212A
Common Name:	Bipolar Vessel Sealing Device
510(k) Number:	K182451 (cleared November 6, 2018)
Manufacturer:	Covidien llc

Device Description
The BiZact™ Tonsillectomy Device Advanced Bipolar Tissue/Divider is a sterile, single use, hand-held electrosurgical device that incorporates radio frequency (RF) tissue fusion technology for a desired tissue effect when used with the ForceTriad™ Energy Platform (Force Triad), the Valleylab™ LS10 Generator (VLLS10GEN), or the Valleylab™ FT10 Energy Platform (VLFT10GEN) for ligation and division of vessels, tissue bundles, and lymphatics during open general surgical procedures.

The BiZact™ Tonsillectomy Device Advanced Bipolar Tissue/Divider attaches to a compatible electrosurgical generator with a 10-foot cord containing a proprietary connector. The generator can identify the BiZact™ Tonsillectomy Device Advanced Bipolar Tissue/Divider via the radiofrequency identification (RFID) tag embedded in the connector (VLLS10GEN and VLFT10GEN) or with a barcode on the connector (ForceTriad). The generator delivers energy to the device using a defined algorithm that adjusts the generator output as a function of the electrical resistance of the tissue.

How Provided
The BiZact™ Tonsillectomy Device Advanced Bipolar Tissue Sealer/Divider is provided sterile and is intended for single use.

Compatible Electrosurgical Generators:

- ForceTriad™ Energy Platform (ForceTriad)
- Valleylab™ LS10 Generator (VLLS10GEN)
- Valleylab™ FT10 Energy Platform (VLFT10GEN)

Indications for Use

The BiZact device is a bipolar instrument intended for use in open surgical procedures where ligation and division of vessels, tissue bundles and lymphatics is desired. The tissue fusion of the device can be used on vessels (arteries and veins) and lymphatics up to and including 3 mm diameter. The BiZact device is indicated for use in open general surgical procedures.

It is also indicated for adult, children and adolescent ENT procedures (3 years of age and above), including tonsillectomy, for the ligation and division of vessels, tissue bundles and lymphatics 2-3 mm away from unintended sensitive structures.

The BiZact device has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use for these procedures.

Patient Contacting Materials

Patient contacting materials included in the manufacture of the BiZact™ Tonsillectomy Device Advanced Bipolar Tissue Sealer/Divider include stainless steel, Polyphthalamide, ceramic, ethylene-tetrafluoroethylene, silicone, and PETE lubricants.

Comparison of Technological Characteristics with the Predicate Device

BiZact™ Tonsillectomy Device Advanced Bipolar Tissue Sealer/Divider is unchanged from the predicate device, as cleared under K182451, in terms of intended use, design, performance, and technological characteristics. The only difference is that the indications for use have been updated to include children population (3 years to less than 12 years). Tonsillectomy is a very well characterized surgical procedure and surgical risks and adverse events are similar for all age ranges. While there is a change in the indicated patient population, the clinical study has demonstrated that the addition of children patients does not raise new questions of safety or effectiveness. Therefore, the subject device is substantially equivalent to the predicate device.

Characteristic	Proposed Device BiZact Device	Predicate Device BiZact Device (K182451)	Comment
Class Regulation	21 CFR §878.4400	21 CFR §878.4400	Same
Class	II	II	Same
Product Code	GEI	GEI	Same
Indications for Use	The BiZact device is a bipolar instrument intended for use in open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The tissue fusion function of the device can be used on vessels (arteries and veins) and lymphatics up to and including 3 mm diameter. The BiZact device is indicated for use in open general surgical procedures. It is also indicated for adult, children and adolescent ENT procedures (3 years of age and above), including tonsillectomy, for the ligation and division of vessels, tissue bundles and lymphatics 2-3 mm away from unintended thermally sensitive structures. The BiZact device has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use for these procedures.	The BiZact device is a bipolar instrument intended for use in open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The tissue fusion function of the device can be used on vessels (arteries and veins) and lymphatics up to and including 3 mm diameter. The BiZact device is indicated for use in open general surgical procedures. It is also indicated for adult and adolescent ENT procedures (12 years of age and above), including tonsillectomy, for the ligation and division of vessels, tissue bundles and lymphatics 2-3 mm away from unintended thermally sensitive structures. The BiZact device has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use for these procedures.	Expansion to include children population.
Contraindications	None	None	Same
Instrument Design	Pistol Grip	Pistol Grip	Same
Energy Type	Electrical (RF) bipolar energy	Electrical (RF) bipolar energy	Same
Compatible Energy Platforms	ForceTriad™ Energy Platform Valleylab™ LS10 Generator Valleylab™ FT10 Energy Platform	ForceTriad™ Energy Platform Valleylab™ LS10 Generator Valleylab™ FT10 Energy Platform	Same
Energy Activation	Handswitch • ForceTriad™ Energy Platform • Valleylab™ LS10 Generator • Valleylab™ FT10 Energy Platform	Handswitch • ForceTriad™ Energy Platform • Valleylab™ LS10 Generator • Valleylab™ FT10 Energy Platform	Same
	Footswitch • ForceTriad™ Energy Platform • Valleylab™ FT10 Energy Platform	Footswitch • ForceTriad™ Energy Platform • Valleylab™ FT10 Energy Platform	Same
Hand-activated Button Design	Single Stage	Single Stage	Same
Proprietary Connector	Yes	Yes	Same
In-Line Activation	Yes	Yes	Same
Cutting Mechanism Design	Integrated cutting blade	Integrated cutting blade	Same
Single Use	Yes	Yes	Same
Sterile	Yes	Yes	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Vessel Size Range	Up to and including 3 mm	Up to and including 3 mm	Same

Performance Characteristics

No design or specification changes are associated with the expanded indication of the BiZact™ Tonsillectomy Device Advanced Bipolar Tissue Sealer/Divider. Evidence of safety and effectiveness was presented in the previously submitted 510(k)s and includes the following:

- Testing in accordance with IEC 60601-1, IEC 60601-1-2, IEC 60601-2-2
- Biocompatibility (ISO 10993-1)
- Device functionality
- Bench burst pressure
- *In vivo* acute and chronic animal studies

Clinical Studies

A prospective, multi-center, single arm clinical study was conducted to demonstrate the safety and effectiveness of the BiZact™ Tonsillectomy Device Advanced Bipolar Tissue/Divider for the use with the pediatric population. Sixty (60) pediatric subjects ranging in age from three (3) to twelve (12) were enrolled in the study and all underwent tonsillectomy with the BiZact™ Tonsillectomy Device Advanced Bipolar Tissue Sealer/Divider. The primary outcome of intra-operative blood loss of the BiZact™ Tonsillectomy Device Advanced Bipolar Tissue Sealer/Divider was significantly less than the benchmark derived from a large meta-analysis, meeting the primary objective.

During the course of the clinical study, adverse events (AEs) were identified and assessed by the Investigators and an Independent External Medical Monitor in terms of severity and relatedness to the device and procedure. The assessment findings were that: a) none (0) of the events were related to use of the BiZact™ Tonsillectomy Device Advanced Bipolar Tissue Sealer/Divider; b) none (0) of the events qualified as serious AEs, and; c) thirteen (13) AEs were related to the tonsillectomy procedure itself. These include fever, vomiting, swollen tongue, throat pain, ear pain, and dehydration. The majority of these tonsillectomy-related AEs were treated at home by caregivers with pain medication. Four (4) subjects with five (5) events of dehydration, received outpatient intervention in the form of IV fluids administered in emergency rooms or a surgery center. None of the subjects were admitted or readmitted to the hospital during this study.

Conclusions

The proposed BiZact™ Tonsillectomy Device Advanced Bipolar Tissue Sealer/Divider with indications for use in Children (3 years to less than 12 years) is substantially equivalent to the predicate BiZact™ Tonsillectomy Device Advanced Bipolar Tissue Sealer/Divider with indications for use in adults and adolescents (12 years of age and above). The clinical study conducted with the proposed device has demonstrated that the subject device is substantially equivalent to the predicate device.