November 6, 2018

Covidien, LLC
Rebecca Clark
Senior Regulatory Affairs Specialist
5920 Longbow Drive
Boulder, CO 80301

Re: K182451
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: September 6, 2018
Received: September 7, 2018

Dear Rebecca Clark:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Srinivas Nandkumar -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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)*
K182451

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 function of the device can be used on vessels (arteries and veins) and lymphatics up to and including 3mm 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.

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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COVIDIEN

510(k) Summary
Date summary prepared: October 30, 2018

510(k) Submitter/Holder
Covidien
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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: K171066 (cleared June 8, 2017)
Manufacturer: Covidien

Device Description
The BiZact™ Tonsillectomy Device Advanced Bipolar Tissue Sealer/Divider is a sterile, single use, hand-held electrosurgical device that incorporates RF tissue fusion technology for a desired tissue effect when used with the ForceTriad Energy Platform (ForceTriad), the Valleylab™ LS10 LS Series Single Channel Vessel Sealing 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 Sealer/Divider attaches to a compatible electrosurgical generator with a 10-foot cord containing a proprietary connector. The generator can identify the BiZact™ device via the 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. The combination of the BiZact instrument and the generator algorithm achieve complete and permanent tissue fusion.

How provided

The BiZact™ Tonsillectomy Device Advanced Bipolar Tissue Sealer/Divider is provided sterile and is intended for single use. It is disposable and provided prescription only.

Provided as viewed in the image below.

Compatible Electrosurgical Generators

BZ4212A, BiZact™ Tonsillectomy Device Advanced Bipolar Tissue Sealer/Divider compatible with:

Code: FORCETRIAD	Code: VLLS10GEN	Code: VLFT10GEN
Force Triad Energy Platform	Valleylab™ LS10 Vessel Sealing Generator	Valleylab™ FT10 Energy Platform

Patient Contacting Materials in BiZact™ Tonsillectomy Device Advanced Bipolar Tissue Sealer/Divider

Patient contacting materials included in the manufacture of the BiZact™ Tonsillectomy Device Advanced Bipolar Tissue Sealer/Divider (BZ4212A) include stainless steel, Polyphthalimide (PPA), ceramic, Ethylene-tetraflouroethylene, silicone, and PFTE lubricants.

Comparison of Technological Characteristics with the Predicate Device

BiZact Tonsillectomy Device Advanced Bipolar Tissue Sealer/Divider (BZ4212A) and is unchanged from the predicate device, as cleared under K171066, in terms of intended use, design, performance, and technological characteristics. The only difference is that the Indications for Use has been changed to include an adolescent population (12-21 years of age).

CHARACTERISTIC	PROPOSED DEVICE BiZact (BZ4212A) **K182451**	PREDICATE DEVICE BiZact (BZ4212A) **K171066**	Comment
Class Regulation	878.44	878.44	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 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.	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 ENT procedures, 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 adolescent in the indication.
Contraindications	None	None	Same
Instrument Design	Pistol Grip	Pistol Grip	Same

Energy Type	Electrical (RF)bipolar energy	Electrical (RF) bipolar energy	Same
CHARACTERISTIC	PROPOSED DEVICE BiZact (BZ4212A)	PREDICATE DEVICE BiZact (BZ4212A)	Comment
Compatible Energy Platform(s) and 510(k)s	Valleylab ForceTriad™ (K102913)	Valleylab ForceTriad™ (K102913)	Same
	Valleylab FT10 Energy Platform, Valleylab FX8 FX Series Energy Platform(K181389)	Valleylab FT10 Energy Platform, Valleylab FX8 FX Series Energy Platform(K181389)	Same
	ValleylabTM LS, LS Series Single Channel Vessel Sealing Generator (K143654)	ValleylabTM LS, LS Series Single Channel Vessel Sealing Generator (K143654)	Same
Energy Activation (Generator)	Handswitch (All compatible generators)	Handswitch (All compatible generators)	Same
	Footswitch (ForceTriad) (Valleylab VLFT10)	Footswitch (ForceTriad) (Valleylab VLFT10)	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	EO	EO	Same
Vessel Size Range	Up to and including 3 mm	Up to and including 3 mm	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 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.

Performance Summary
Verification and validation results demonstrate that the BiZact Adolescent Tonsillectomy Device Advanced Bipolar Tissue Sealer/Divider performs as intended. The following summarizes testing conducted to establish safety and substantial equivalence:

- IEC 60601-1 Basic Electrical Safety
- IEC 60601-1-2 Electromagnetic Compatibility
- IEC 60601-2-2 Basic Safety for HF Equipment and HF Accessories
- ISO 10993-1 Biocompatibility
- Performance Testing – Device Functionality
- Performance Testing – Bench Tissue – burst testing (renal artery and lymph)
- Performance Testing – In-vivo – acute (hemostasis, thermal spread) and chronic (hemostasis)

No design or specification changes are associated with expanded indication, therefore the previous performance testing listed above remains applicable.

Clinical Literature Summary
A study of clinical literature for tonsillectomy procedures in adults and adolescents show that treatments in tonsillectomy considering risk factors such as bleeding, and anatomical measurements of the treatment area in adults and adolescents are very similar without creating additional risk concerns for using the BiZact device to perform ENT procedures in both populations.

Conclusion on Substantial Equivalence
The proposed BiZact Tonsillectomy Device Advanced Bipolar Tissue Sealer/Divider (BZ4212A) for use in adolescents defined as (12-21 years of age in this submission) is substantially equivalent to the predicate BiZact Tonsillectomy Device Advanced Bipolar Tissue Sealer/Divider (BZ4212A) for use in adults defined as (22+ years of age). Supporting clinical literature attached to this submission shows that inclusion of adolescents in the indications for this device do not raise new questions of safety or efficacy.

All performance and design specifications remain the same as for the previously cleared design. Therefore, the subject device is substantially equivalent to the 510(k) cleared predicate device.