



Food and Drug Administration
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June 15, 2016

Covidien
Ms. Sharon McDermott
Senior Product Specialist Regulatory Affairs
5920 Longbow Drive
Boulder, Colorado 80301

Re: K160539

Trade/Device Name: Bizact Open 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: May 24, 2016
Received: May 25, 2016

Dear Ms. McDermott:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K160539

Device Name
BiZact Open 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 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.

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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510(k) Summary

Date summary prepared: June 10, 2016

510(k) Submitter/Holder

Covidien, llc
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Contact

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Name of Device

Trade Name: BiZact™ Open Sealer/Divider
Common Name: Bipolar electrosurgical instrument
Classification Name: Electrosurgical cutting and coagulation device and accessories (21 CFR § 878.4400, class II, GEI).

Predicate Devices

The BiZact, Open Sealer/Divider was compared and found to be substantially equivalent to the following products of comparable type in commercial distribution:

Device Common Name:	Bipolar electrosurgical instrument
Trade Name:	LigaSure™ Small Jaw, Open Sealer/Divider
Catalog Number:	LF1212A
510(k) Number:	K152286
Manufacturer:	Covidien, llc

Device Description

The BiZact Open Sealer/Divider is sterile, single use, hand-held electrosurgical device that incorporates RF tissue fusion technology for a desired tissue effect when used with the Valleylab™ LS10 Vessel Sealing Generator for ligation and division of vessels, tissue bundles, and lymphatics during open general surgical procedures.

The BiZact attaches to the Valleylab LS10 Vessel Sealing Generator with a 10 foot cord containing a connector. The generator is able to identify the BiZact device via the RFID tag embedded in the connector. The generator delivers precise energy through the device to tissue for a controlled tissue response to achieve complete and permanent tissue fusion by incorporating tissue sensing circuitry to constantly measure the electrical resistance of the tissue and instantaneously adjust the generator output to maintain the desired power.

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 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.

Testing Summary:

Verification and validation results demonstrate that the BiZact Open Sealer/Divider performs as intended and is substantially equivalent to its predicate, LF1212A. 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
- Performance Testing – In-vivo – acute (hemostasis, thermal spread, lymphatic burst pressure,) and chronic (hemostasis)
- Usability – Design Validation – Summative testing in simulated use environment

Conclusion on Substantial Equivalence

The proposed BiZact Open Sealer/Divider is substantially equivalent to the predicate LigaSure Small Jaw Open Sealer/Divider. Both devices have the same intended use and fundamental technology. The proposed device has some intentional design and indications differences that enable it to be well suited for its indicated uses. Testing demonstrated that these differences do not raise any new questions of safety or effectiveness.