



Food and Drug Administration
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February 18, 2016

Ent Biotech Solutions
Laura Yamada
Regulatory Affairs
75 Lewiston Road
Gross Pointe Farms, Michigan 48236

Re: K152702

Trade/Device Name: ENT Biotech Solutions Tissue Removal Device (Elasso)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 15, 2016
Received: January 19, 2016

Dear Ms. Yamada:

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,

Eric A. Mann -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K152702

Device Name

ENT Biotech Solutions Tissue Removal Device (Elasso™)

Indications for Use (Describe)

The ENT Biotech Solutions Tissue Removal Device (Elasso™) is intended to be used for the cutting and coagulation of soft tissue during otolaryngology (ENT) surgery including de-bulking adenoid and tonsil tissue (Pharyngeal, Tubal, and Palatine).

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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Premarket Notification [510(k)] Summary

Category	Comments
Date Summary Prepared:	September 8, 2015
Applicant:	ENT Biotech Solutions, INC 75 Lewiston Road Grosse Pointe Farms, MI 48236 USA Tel: 1.313.922.4615 Email: Adickson@entbiotechsolutions.com
Applicant's Contact Information:	Laura Yamada or Andrea Dickson Email: Laura.Yamada@sbcglobal.net
Device Trade/ Proprietary Name:	ENT Biotech Solutions tissue removal device (Elasso™)
Device Common Name:	Electrosurgical, Cutting & Coagulation Device & Accessories
Device Product Code:	GEI
Device Classification / Name:	II / Electrosurgical, Cutting & Coagulation Device & Accessories
CFR Citation:	21 CFR 878.4400

Substantial Equivalence Device Information**510(k) Summary – Predicate Device Information**

Predicate Device(s):	PEAK Plasmablade™ TNA Tonsil and Adenoid Tissue Dissection Device
Predicate Device Manufacturers:	Medtronic (Formerly PEAK Surgical, Inc)
510(k) Number:	K083415
Predicate Device Common Name:	Electrosurgical, Cutting & Coagulation Device & Accessories
Predicate Device Classification Name & Citation:	Electrosurgical, Cutting & Coagulation Device & Accessories, 21 CFR 878.4400

Description of the Device

The ENT Biotech Solutions tissue removal device (also referred to as the “Elasso™”) is a single-use, surgical accessory, used with a recommended electrosurgical generator (not supplied by ENT Biotech Solutions, INC) and associated equipment (monopolar cord and patient return electrode). The Elasso device configuration is similar to a standard forceps geometry (patterned after the commercially available reference device, St. Clair Forceps), but with an integrated loop electrode at the distal tip of one of the arms of the forceps. The proximal

end contains a single banana plug. for connection to the generator. The hand piece is operated by the generator's footswitch controller.

The Elasso™ is a single-use, sterile packaged device.

Indications for Use / Intended Use

The Elasso™ tissue removal device is intended to be used for the cutting and coagulation of soft tissue during otolaryngology (ENT) surgery including de-bulking of adenoid and tonsil tissue (Pharyngeal, Tubal, and Palatine).

Technological Characteristics

The Elasso™ device is similar to the predicate device in that they are both electrosurgical instruments used to cut and coagulate soft tissue utilizing RF energy. The Elasso device differs from the PEAK device in the hand piece design. However, both devices incorporate partially exposed electrode elements which allow for application of RF energy, such that the principles of operation involved in cutting and coagulation of tissue are the same on either device with respect to energy density. Also, the results of a comparison study indicate that the thermal spread produced by the Elasso device across its specified use settings does not significantly exceed the thermal spread produced by the predicate device. In addition, the Elasso's forcep-like design is patterned after the geometry of the commercially available reference device, St. Clair Forceps device which is used to remove adult and pediatric tissue and has been over many decades as an acceptable tool for access to the indicated tissues. The differences identified do not present any new concerns of safety and effectiveness.

Table 6-1: Comparison Table

Description	Predicate	ENT Biotech Solutions
General		
Intended Use	Intended to be used for the cutting and coagulation of soft tissue during otolaryngology (ENT) surgery including adenoidectomy and tonsillectomy (Pharyngeal, Tubal, Palatine).	Intended to be used for the cutting and coagulation of soft tissue during otolaryngology (ENT) surgery including de-bulking of adenoid and tonsil tissue (Pharyngeal, Tubal, and Palatine).
Principles of operation	Electrosurgical cutting and coagulation device intended to remove tissue and coagulate by use of radio frequency (RF) energy.	Same
Anatomical Site	Soft Tissue in ENT surgeries	Same
Target Population	Patients requiring ENT surgeries	Same
Use	Single-Use	Same
Materials	Metal electrode element/polymer insulator	Same
Specifications		
Energy Delivered	Radio frequency	Same

Description	Predicate	ENT Biotech Solutions
Rated Voltage	5,000V peak to peak	5,000V (or 10,000V peak to peak)
Max Power Output	50W	50W
Power Modes	Monopolar	Same
Design	Light weight hand piece (wand-like) connected via cable to generator	Light weight hand piece (forceps-like similar to the commercially available St. Claire Forceps) connected via cable to generator
Hand Piece Tip	Tonsil tip: curved electrode element housed in a plastic tip Adenoid tip: straight electrode element housed in a plastic tip	Curved electrode element housed in a plastic tip
Overall Length	210mm (Tonsil Tip)/245mm (Adenoid Tip)*	200.4mm
Compliance		
Sterilization	Provided Sterile (Ethylene Oxide)	Provided Sterile to SAL of 10 ⁻⁶ (Gamma Radiation, per ISO 11137-1:2006 and ISO 11137-2:2006)
Electrical Standards	Unknown	IEC 60601-1:2012, IEC 60601-1-2:2007, IEC 60601-2-2:2009
Biocompatibility	Unknown	ISO 10993-1:2009, 510(k) Memorandum – #G95-1: Use of International Standard ISO-10993

*191.5mm (St. Claire Forceps)

Summary of Studies

Performance testing was conducted on the Elasso device to demonstrate compliance with the product requirements and to demonstrate safety and efficacy and substantial equivalence to the predicate. The following product performance tests are included: mechanical, electrical safety/electromagnetic compatibility, operational, *in-vivo* evaluation, *ex-vivo* thermal effects on tissue comparisons, thermal modeling, usability/device access, biocompatibility, sterility and packaging / shelf life evaluation. Like the predicate device, no clinical testing was deemed necessary to support substantial equivalence. The data submitted support the substantial equivalence claim for the proposed indications for use; the Elasso is as safe and effective as the predicate device.

Conclusion

ENT Biotech Solutions, INC considers the Elasso device to be substantially equivalent to the legally marketed predicate device with respect to the device function, intended use, patient population and anatomical site. Any differences in technological characteristics between the Elasso device and the predicate device do not raise any new issues of safety and effectiveness.