November 25, 2020

Bryan Medical, Inc.
% Ian Broome
Regulatory Affairs Consultant
AlvaMed, Inc.
1116 Great Plain Avenue, Suite 1
Needham, Massachusetts 02492

Re: K200761
Trade/Device Name: Tenax Laser Resistant Endotracheal Tube
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR, BSK
Dated: October 23, 2020
Received: October 26, 2020

Dear Ian Broome:

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,

Todd Courtney
Assistant 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)*
K200761

Device Name
Tenax® Laser Resistant Endotracheal Tube

Indications for Use *(Describe)*
The Tenax® Laser Resistant Endotracheal Tube is intended for endotracheal intubation. It is indicated for use for all types of surgical procedures involving carbon dioxide (10.60 microns) or KTP (532 nm) laser use (normal pulsed or continuous beam delivery in the non-contact mode), when endotracheal intubation is required to administer anesthetic gases or to overcome emergency obstruction of an airway.

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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5.0 TRADITIONAL 510(K) SUMMARY FOR TENAX® LASER RESISTANT ENDOTRACHEAL TUBE

K200761

I. SUBMITTER

Bryan Medical, Inc.
5725 Dragon Way, Suite 300
Cincinnati, OH 45227

Phone: (888) 331-3485, x 700

Fax: (617) 249-0955

Contact Person: Ian Broome, AlvaMed, Inc.

Date Prepared: November 23, 2020

II. DEVICE

Name of Device: Tenax® Laser Resistant Endotracheal Tube

Common or Usual Name: Endotracheal tube (cuffed)

Classification Name: Tracheal tube (21 CFR 868.5730)

Regulatory Class: II

Product Code: BTR, BSK

III. PREDICATE DEVICE

Laser-Shield® II, K993582

IV. DEVICE DESCRIPTION

The Tenax® Laser Resistant Endotracheal Tube is an endotracheal tube with two inflatable cuffs. It is indicated for use in surgical procedures where intubation is required in the presence of KTP or CO_2 lasers.

The device is provided sterile (EO). After use, the device is discarded and disposed of in accordance with local regulations. There are no associated device accessories.

V. INDICATION FOR USE

The Tenax® Laser Resistant Endotracheal Tube is intended for endotracheal intubation. It is indicated for use for all types of surgical procedures involving carbon dioxide (10.60 microns) or KTP (532 nm) laser use (normal pulsed or continuous beam delivery in the non-contact mode), when endotracheal intubation is required to administer anesthetic gases or to overcome emergency obstruction of an airway.

Intended Population:	Adults (≥ 22 years old) requiring endotracheal intubation during laser surgery procedures in the upper gastro-respiratory tract.
Intended Environment of Use:	Trachea/Upper GI Tract
Contraindications:	• The Tenax® Laser Resistant Endotracheal Tube should not be used in patients with narrow airways, which could restrict ventilation, resulting in excessive elevation of intratracheal pressure. • Do not use in any patient suffering from conditions that may preclude endotracheal intubation. Do not use this device for any purpose other than its intended use. • To avoid device damage, do not exceed a power density of 10,394 W/cm^2 when used with a CO_2 laser. • To avoid device damage, do not exceed a power density of 5,305 W/cm^2 when used with a KTP laser. • Do not use with continuous irradiation lasting longer than 30 seconds.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Subject: **Tenax® Laser Resistant Endotracheal Tube**	**Predicate Device:** **Laser-Shield® II**
Manufacturer	Bryan Medical, Inc.	Medtronic/Xomed
510(k) Number	K200761	K993582
Product Code	BTR, BSK	BTR
Regulation	868.5730	868.5730
Regulation Description	Tracheal tube	Tracheal tube
Common Name	Endotracheal tube	Endotracheal tube
Indications for Use	The Tenax® Laser Resistant Endotracheal Tube is intended for endotracheal intubation. It is indicated for use for all types of surgical procedures involving carbon dioxide (10.60 microns) or KTP (532 nm) laser use (normal pulsed or continuous beam delivery in the non-contact mode), when endotracheal intubation is required to administer anesthetic gases or to overcome emergency obstruction of an airway.	Xomed Laser-Shield® II is intended for endotracheal intubation. It is indicated for use for all types of surgical procedures involving carbon dioxide (10.60 microns) or KTP (532 nm) laser use (normal pulsed or continuous beam delivery in the non-contact mode), when endotracheal intubation is required to administer anesthesia gases or to overcome emergency obstruction of an airway.
Sterility	Sterile (ethylene oxide) SAL 10^{-6}	Sterile (method unknown)
Biocompatibility Classification	Surface Device, Mucosal Membrane, Limited Duration (< 24h)	Surface Device, Mucosal Membrane, Limited Duration (< 24h)
Design Features	• Endotracheal tube with cuffs at distal end • Aluminum wrapping for laser resistance • Outer atraumatic silicone covering • Blue dye within pilot balloons for leak/damage indication	• Endotracheal tube with cuffs at distal end • Aluminum wrapping for laser resistance • Outer atraumatic polymer covering • Blue dye within pilot balloons for leak/damage indication

	Subject: **Tenax® Laser Resistant Endotracheal Tube**	**Predicate Device:** **Laser-Shield® II**
Connection to Ventilation Source	Standard straight connector to anesthesia gas supply	Standard straight connector to anesthesia gas supply
Dimensions	Length: 34cm ID: (6 sizes) • 5.0mm (model TG-0050) • 5.5mm (TG-0055) • 6.0mm (TG-0060) • 6.5mm (TG-0065) • 7.0mm (TG-0070) • 7.5mm (TG-0075) OD: • 7.9mm (TG-0050) • 8.6mm (TG-0055) • 9.3mm (TG-0060) • 10.0mm (TG-0065) • 10.6 (TG-0070) • 11.0mm (TG-0075)	Length: 33cm ID: (9 sizes) • 4.0mm (model 7060100) • 4.5mm (7060150) • 5.0mm (7060200) • 5.5mm (7060250) • 6.0mm (7060300) • 6.5mm (7060350) • 7.0mm (7060400) • 7.5mm (7060450) • 8mm (7060500) OD: • 6.6mm (7060100) • 7.3mm (7060150) • 8.0mm (7060200) • 8.6mm (7060250) • 9.0mm (7060300) • 10.0mm (7060350) • 10.5mm (7060400) • 11.0mm (7060450) • 11.5mm (7060500)
Single Use?	Yes	Yes

Both devices are laser resistant endotracheal tubes. They share an identical indication for use and are intended for use in the same manner. The subject and predicate devices also share the following technological characteristics:

- Laser resistance using an inner aluminum scattering layer,
- Atraumatic outer layer for protection of patient tissue,
- Inflatable cuffs,
- Use of internal dye as a warning indicator to alert practitioners of device puncture or damage.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

- Dimensional testing,
- Bend radius,
- Cuff inflation/deflation/burst testing (time and pressure),
- Dye visibility,
- Laser resistance,
- Tracheal tube dimensions,
- Connector leakage.
-

Biocompatibility Testing

The biocompatibility evaluation for the Tenax® Laser Resistant Endotracheal Tube was conducted in accordance with the FDA's guidance "International Standard ISO 10993-1 'Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process.'" The biocompatibility testing included the following tests:

- Cytotoxicity,
- Sensitization,
- Irritation,
- Acute Systemic Toxicity,
- Material-Mediated Pyrogenicity.

The Tenax® Laser Resistant Endotracheal Tube is considered tissue-contacting for a duration of less than 24 hours. The device's materials are well-characterized for medical use.

VIII. CONCLUSIONS

The non-clinical test data support the safety of the device and the verification and validation testing data demonstrate that the Tenax® Laser Resistant Endotracheal Tube shall perform as intended in the specified use conditions. The subject device and the predicate device have the same intended use, and the technological differences do not raise different questions of safety and effectiveness.