January 16, 2024

Thoracent, Inc.
% Bosmat Friedman
Regulatory Consultant
ProMedoss, Inc.
3521 Hatwynn Rd.
Charlotte, North Carolina 28269

Re: K223266
Trade/Device Name: Hilzo Esophageal Stents
Regulation Number: 21 CFR 878.3610
Regulation Name: Esophageal Prosthesis
Regulatory Class: Class II
Product Code: ESW
Dated: April 26, 2023
Received: April 26, 2023

Dear Bosmat Friedman:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).
Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Sivakami Venkatachalam -S

for
Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital, and Urology 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223266

Device Name
Hilzo Esophageal Stents

Indications for Use *(Describe)*
The HILZO Esophageal Stents are indicated for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

[as required by section 807.92(c)]

HILZO Esophageal Stent

510(k) Number K223266

5.1 SUBMITTER

Applicant's Name:
Thoracent, Inc.
Brian Lynch, CEO
11 Stewart Ave.
Unit 1, Suite 200
Huntington, NY, USA
917-4396742
brian@thoracent.com

Contact Person:
Bosmat Friedman
Regulatory Affairs Consultant
3521 Hatwynn Rd.
Charlotte, NC 28269
Phone: 980-308-1636
bosmat.f@promedoss.com

Date Revised:
December 14, 2023

5.2 DEVICE

Trade Name:
HILZO Esophageal Stents

Classification Code:	**Device:**	Prosthesis, Esophageal
	Product Code:	ESW
	Regulation No:	878.3610
	Class:	2
	Medical Specialty:	General & Plastic Surgery
	Review Panel:	Gastroenterology/Urology

5.3 PREDICATE DEVICE

Primary Predicate:

- Niti-S Esophageal Stent System, manufactured by Taewoong Medical Co., Ltd., cleared under K080782; Product Code: ESW

Reference devices for

- Esophageal TTS Stent, manufactured by Taewoong Medical Co., Ltd., cleared under K123205; Product Code: ESW.
- Bonastent Esophageal, manufactured by EndoChoice, Inc. cleared under K092144; Product Code: ESW

5.4 DEVICE DESCRIPTION

The HILZO Esophageal Stents are partially covered and fully covered, self-expanding tubular prosthesis designed to maintain patency of esophageal strictures. The HILZO Esophageal stents are available loaded on two styles of delivery devices, Over the Wire (OTW) and Through the Scope (TTS). The OTW delivery devices are 14Fr and the TTS is 10.5Fr to enable delivery through the working channel of an endoscope. The stents are made of Nitinol wire and are designed to prevent stent migration due to peristaltic motion and tumor in-growth. The stents are available in a variety models, diameters and lengths.

5.5 INDICATIONS FOR USE

The HILZO Esophageal Stents are indicated for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors.

5.6 SUBSTANTIAL EQUIVALENCE

The subject and predicate devices are both single- use, partially covered and fully covered esophageal stents indicated for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors. The stent weave pattern, delivery devices as well as the available stent sizes are equivalent in design and performance.

The following table provides a comparison with the predicate:

Feature	HILZO Esophageal Stent	Niti-S Esophageal (OTW) K080782	Comparison to Predicate
Reg. Number	878.3610	878.3610	Same
Product Code	ESW	ESW	Same
Indication for Use	The HILZO Esophageal Stents are indicated for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors	Niti-S Esophageal Stent is intended for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors.	Same
Principle of Operation	TTS and OTW models available	OTW	Same as both devices
Biocompatibility	Biocompatible per ISO 10993	Biocompatible per ISO 10993	Same
Single use	Yes	Yes	same

Feature	HILZO Esophageal Stent	Niti-S Esophageal (OTW) K080782	Comparison to Predicate
Sterility	Eto	Eto	Same
Stent material	Nitinol	Nitinol	Same
Covering material	Silicone/PTFE	Silicone	Similar; biocompatibility testing supports the safety and effectiveness profile of the HILZO Esophageal Stent; literature survey and material tensile strength testing support the use of PTFE cover material
Stent diameter (mm)	18-20 mm	16 – 20 mm	Same; compression and expansion testing support the stent diameter difference
Stent total length (mm)	60-150 mm	60-120 mm	Similar; compression and expansion testing support the increased stent length; FDA has cleared other esophageal stents with a length of 150 such as K172813 and K211706
Stent head	Silicone covered and uncovered flaring stent head design with/without removal string (lasso)	Silicon covered and uncovered flaring stent head design with/without removal string (lasso)	Similar flaring stent head design
Delivery Diameter	OTW – 14 Fr, 16 Fr TTS – 10.5 Fr	OTW – 16 Fr and 20 Fr	Similar; deployment testing and tensile strength testing demonstrate delivery device performance
MR Status	MR Conditional	MR Conditional	Same
Expansion force	Fully Covered: 18X60 – Avg. 0.442 kgf 18X150 – Avg. 0.443 kgf 20X60 – Avg. 0.520 kgf 20X150 – Avg. 0.460 kgf Partial Covered: 18X60 – Avg. 0.445 kgf 18X150 – Avg. 0.446 kgf 20X60 – Avg. 0.528 kgf 20X150 – Avg.0.537 kgf	Fully Covered: 18X60 – Avg. 0.439 kgf 18X150 – Avg. 0.443 kgf 20X60 – Avg. 0.521 kgf 20X150 – Avg. 0.543 kgf Partial Covered: 18X60 – Avg. 0.440 kgf 18X150 – Avg. 0.448 kgf 20X60 – Avg. 0.530 kgf 20X150 – Avg.0.542 kgf	Similar; all results fell within the ±5% difference acceptance criteria. The results support our SE claim
Compression force	Fully Covered: 18X60 – Avg. 3.073 kgf 18X150 – Avg. 3.189 kgf 20X60 – Avg. 3.75 kgf 20X150 – Avg. 3.844 kgf Partial Covered: 18X60 – Avg. 3.097 kgf 18X150 – Avg. 3.176 kgf 20X60 – Avg. 3.876 kgf 20X150 – Avg.3.925 kgf	Fully Covered: 18X60 – Avg. 3.093 kgf 18X150 – Avg. 3.168 kgf 20X60 – Avg. 3.786 kgf 20X150 – Avg. 3.889 kgf Partial Covered: 18X60 – Avg. 3.141 kgf 18X150 – Avg. 3.220 kgf 20X60 – Avg. 3.875 kgf 20X150 – Avg.3.914 kgf	Similar; all results fell within the ±5% difference acceptance criteria. The results support our SE claim

Any differences in technological characteristics do not raise different questions of safety or effectiveness.

5.7 PERFORMANCE DATA

The following performance data is provided in support of the substantial equivalence determination.

Biocompatibility:

The stent and delivery system underwent extensive biocompatibility data in accordance with guidance document: *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*. Per the obtained results, the HILZO Esophageal Stent System was found to be biocompatible.

Non-Clinical Performance Testing:

The HILZO Esophageal Stents have undergone and successfully passed the following:

- Shelf-life and sterilization validation
- Expansion force testing
- Compression force testing
- Dimensional testing
- Corrosion testing
- Kink resistance testing
- Tensile strength testing (delivery system)
- Tensile strength test (cover material)
- Deployment force and deployment positioning testing
- Suture Loop Tensile Strength Testing
- Radiopacity testing
- MR safety

5.8 CONCLUSION

The HILZO Esophageal Stents have the same indications for use and technological characteristics as its predicates, Niti-S and Esophageal. The company has provided sufficient comparative testing between the HILZO Esophageal Stents and the predicates, as well as additional pre-clinical bench data to demonstrate our substantial equivalency claim. Consequently, it is clear that the HILZO Esophageal Stents are as safe and effective as their primary predicates without raising any new safety and/or effectiveness concerns.