March 22, 2024

Taewoong Medical
℅ Matthew Krueger
Senior Consultant
Biologics Consulting Group
100 Daingerfield Road, Suite 400
Alexandria, Virginia 22314

Re: K240522
Trade/Device Name: Esophageal TTS Stent
Regulation Number: 21 CFR 878.3610
Regulation Name: Esophageal Prosthesis
Regulatory Class: Class II
Product Code: ESW
Dated: February 23, 2024
Received: February 23, 2024

Dear Matthew Krueger:

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,

Shanil P. Haugen -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240522

Device Name

Esophageal TTS Stent

Indications for Use *(Describe)*

The Esophageal TTS Stent is intended for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors and occlusion of concurrent esophageal fistulas.

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.

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1. SUBMITTER INFORMATION

Applicant:	Taewoong Medical
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Email:	jinjeff@stent.net
Address	14, Gojeong-ro, Wolgot-myeon, Gimpo-si, Gyeonggi-do, 10022, Republic of Korea

2. CORRESPONDENT INFORMATION

Contact:	Matthew Krueger
Title:	Senior Consultant
Firm:	Biologics Consulting Group

3. DATE PREPARED: FEBRUARY 21, 2024

4. DEVICE INFORMATION

Device Name:	Esophageal TTS Stent
Common Name:	Prosthesis, Esophageal
Regulation Number:	21 C.F.R. 878.3610
Regulation Name:	Esophageal prosthesis
Product Code:	ESW
Regulatory Class:	Class II

5. PREDICATE DEVICE INFORMATION

Device Name:	Taewoong Esophageal TTS Stent
510(k) Number:	K221482
Manufacturer:	Taewoong Medical

The predicate device has not been subject to a design related recall.

6. DEVICE DESCRIPTION

The Esophageal TTS Stents that are the subject of this 510(k) are identical to the devices cleared in K221482, with the exception of the modification to its introducer system. The Esophageal TTS Stents consist of an implantable metallic stent and a disposable, flexible introducer system

for placement of the stent. The stent is a flexible and expandable tubular device made of Nitinol wire that is intended to be implanted to restore the structure and/or function of the esophagus. The introducer is a disposable system for delivery and deployment of the stent at the target position. Upon deployment, the stent imparts an outward radial force on the luminal surface of the esophagus to establish patency.

7. INDICATIONS FOR USE

The Esophageal TTS Stent is intended for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors and occlusion of concurrent esophageal fistulas.

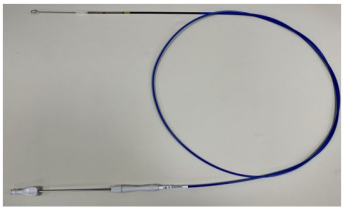
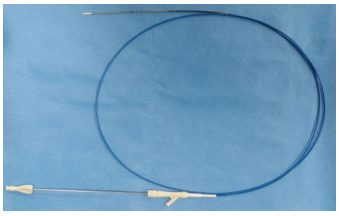
8. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The table below compares the intended use and the technological characteristics of the subject device and predicate device.

Table 1: Comparator Table for Subject and Predicate Devices

	Subject Device	**Predicate Device K221482**	**Comments**
Device Name	Esophageal TTS Stent	Esophageal TTS Stent	Identical
Common Name	Esophageal Stent	Esophageal Stent	Identical
Manufacturer	Taewoong Medical Co., Ltd	Taewoong Medical Co., Ltd	Identical
Product Code	ESW	ESW	Identical
Regulation	21 CFR 878.3610 Esophageal prosthesis	21 CFR 878.3610 Esophageal prosthesis	Identical
Indications for use	For use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors and occlusion of concurrent esophageal fistulas.	For use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors and occlusion of concurrent esophageal fistulas.	Identical

	Subject Device	**Predicate Device K221482**	**Comments**
Design (Stents)	 Full Covered Stent  Both Bare Stent Nitinol wire in diamond shape Lengths; 60, 80, 100, 120, 140, 150mm Body Diameter/Head Diameter: · 18mm/26mm · 20mm/26mm · 22mm/28mm Coverage: · Silicone Full Covered · Silicone Both Bare Radiopaque Markers: 8 Pt/Ir, 2 STS 316L	 Full Covered Stent  Both Bare Stent Nitinol wire in diamond shape Lengths; 60, 80, 100, 120, 140, 150mm Body Diameter/Head Diameter: · 18mm/26mm · 20mm/26mm · 22mm/28mm Coverage: · Silicone Full Covered · Silicone Both Bare Radiopaque Markers: 8 Pt/Ir, 2 STS 316L	Identical

	Subject Device	Predicate Device K221482	Comments
Design (Introducer)	 Co-axial tube type Usable Length: 180 and 220cm Diameter: 10.5 Fr (3.5mm)	 Co-axial tube type Usable Length: 180 and 220cm Diameter; 10.5 Fr (3.5mm)	**Substantially Equivalent** Dimensionally the same General design is identical with the following changes: 1) Hub: Changes from ABS to PCABS (not patient contacting) 2) Replacement of Y-Connector with a straight connector (PCABS) (no side port like the Y-connector) (not patient contacting) 3) 2nd Inner Catheter material change from Nylon to Nylon with black pigment (not patient contacting) 4) Yellow marker changing from Nylon to Acrylic Resin with Tampa Pur TPU 122 (yellow colorant) (patient contacting) 5) Addition of heat shrinkable tube at distal end of the connector (not patient contacting) 6) Soft 2nd Inner Catheter made of Nylon 6/6 added to provide flexibility between the 1st and 2nd inner catheters (patient contacting) 7) Addition of lubricant to the inner catheter to decrease deployment force (not patient contacting) Performance testing and biocompatibility testing demonstrates that the changes to design and materials do not affect the safety or effectivness
Single Use	Yes	Yes	Identical
Sterile	EO Sterilization	EO Sterilization	Identical

	Subject Device	Predicate Device K221482	Comments
Method of Placement	Endoscopic	Endoscopic	Identical
Method of Deployment	Release by pulling outer sheath	Release by pulling outer sheath	Identical
Packaging	PET tray with Tyvek lid placed in a Tyvek pouch and then placed inside of a Manila paper box	PET tray with Tyvek lid placed in a Tyvek pouch and then placed inside of a Manila paper box	Identical

9. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Biocompatibility Testing

Biocompatibility testing of the stent was not repeated for this submission since the stent in this submission is identical to the stent cleared in K221482. The stent, in its final finished form, is identical to the Esophageal TTS Stent in formulation, processing, sterilization, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents).

Patient contacting materials of the introducer:

The following parts directly contact patient tissue for <24 hours:

- outer sheath
- soft 2nd inner catheter
- yellow marker
- proximal/center/distal X-ray markers
- holder
- 1st inner catheter
- tip

Table 2: Biocompatibility Testing Conducted

Cytotoxicity MEM Extract	ISO 10993-5:2009
Sensitization Guinea pig maximization test	ISO 10993-10:2021
Intracutaneous Reactivity New Zealand rabbit	ISO 10993-23:2021
Acute Systemic Toxicity ICR mice	ISO 10993-11:2017
Pyrogen Test New Zealand rabbit	ISO 10993-11:2017 USP <151>

Electrical Safety

Not applicable. The subject device contains no electric components, generates no electrical emissions, and uses no electrical energy of any type.

Electromagnetic Compatibility (EMC)

Not applicable. The subject device contains no electric components, generates no electrical emissions, and uses no electrical energy of any type.

Software

Not applicable. The subject device contains no software.

Performance Testing

Other performance testing was conducted to show that the device meets its design requirements and performs as intended. The performance tests include:

- Deployment Test
- Deployment Force Test
- Dimensional Test
- Tensile Strength Test

10. CONCLUSION

The results of the performance testing described above demonstrate that the TTS Esophageal Stent is as safe and effective as the predicate device and supports a determination of substantial equivalence.