October 30, 2025

Taewoong Medical Co., Ltd.
℅ Matthew Krueger
Principal Consultant
Biologics Consulting Group
100 Daingerfield Rd, Suite 400
Alexandria, Virginia 22314

Re: K243619
Trade/Device Name: Niti-S Esophageal Stent; Esophageal TTS Stent
Regulation Number: 21 CFR 878.3610
Regulation Name: Esophageal Prosthesis
Regulatory Class: Class II
Product Code: ESW
Dated: September 29, 2025
Received: September 29, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K243619

Please provide the device trade name(s).

Niti-S Esophageal Stent;
Esophageal TTS Stent

Please provide your Indications for Use below.

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

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

1. SUBMITTER INFORMATION

Applicant:	Taewoong Medical
Contact:	Yongjin Jeff Kim
Phone:	+82 70 4649 1543
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:	Principal Consultant
Firm:	Biologics Consulting Group

3. DATE PREPARED: SEPTEMBER 25, 2024

4. DEVICE INFORMATION

Device Name:	Esophageal TTS Stent Niti-S Esophageal 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:	Esophageal TTS Stent, Niti-S Esophageal Stent
510(k) Number:	K240522, K080782
Manufacturer:	Taewoong Medical

The predicate devices have not been subject to a design related recall.

6. DEVICE DESCRIPTION

The Esophageal TTS Stents and Niti-S Esophageal Stents that are the subject of this 510(k) are identical to the devices cleared in K240522 and K080782, respectively, with the exception of the change in suture material for both stents. The indications for use for the Niti-S Esophageal Stent have also been updated to align with those of the Esophageal TTS Stents.

The Esophageal TTS Stents and Niti-S Esophageal 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. A length of suture is attached to one end of the stent and can be used for stent repositioning during initial placement, in accordance with the instructions for use.

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.

The Niti-S Esophageal 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

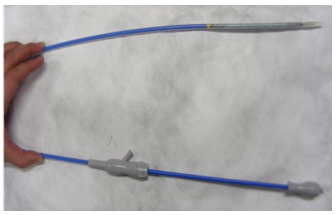
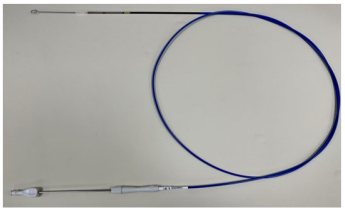
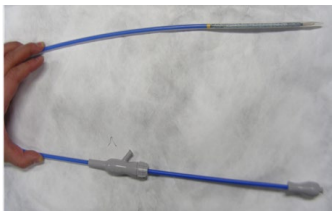
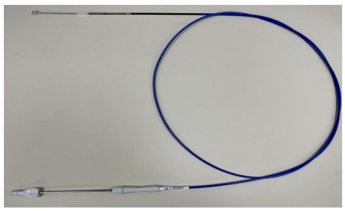
The table below compares the intended use and the technological characteristics of the subject device and predicate device.

Table 1: Comparator Table for Subject and Predicate Devices

	Subject Device	**Predicate Device K080782, K240522**	**Comments**
Device Name	Niti-S Esophageal Stent, Esophageal TTS Stent	Niti-S Esophageal Stent (K080782), Esophageal TTS Stent (K240522)	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

	Subject Device	Predicate Device K080782, K240522	Comments
Indications for use	Niti-S Esophageal Stent is intended for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors and occlusion of concurrent esophageal fistulas. Esophageal TTS Stent is intended for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors and occlusion of concurrent esophageal fistulas.	(K080782) Niti-S Esophageal Stent is intended for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors. (K240522) Esophageal TTS Stent is intended for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors and occlusion of concurrent esophageal fistulas.	**Substantially Equivalent:** • Original use of K080782: esophageal strictures from malignant tumors • Now includes: "occlusion of concurrent esophageal fistulas". This indication was previously cleared for the identical stent implant as cleared in K240522. • Stent Justification: o Same materials o Same design o Same purposes o Same target site o Same manufacturing process • Therefore, the Niti-S Esophageal Stent with the modified Indications for Use is Substantially Equivalent to the previously cleared Esophageal TTS Stent (K240522).

	Subject Device	Predicate Device K080782, K240522	Comments
Design (Stents)	 Full Covered Stent  Both Bare Stent ▪ Nitinol wire in diamond shape ▪ Lengths: 60 mm, 80 mm, 100 mm, 120 mm, 140 mm, 150 mm ▪ Midsection Diameters: 16 mm, 18 mm, 20 mm, 22 mm ▪ Dumbbell Diameters: 24 mm, 26 mm, 28 mm ▪ Coverage: Silicone Full Covered, Silicone Both Bare ▪ Radiopaque Markers: 8 platinum-iridium markers and 2 316L stainless steel markers ▪ Suture material: Polyester	 Full Covered Stent  Both Bare Stent ▪ Nitinol wire in diamond shape ▪ Lengths: 60 mm, 80 mm, 100 mm, 120 mm, 140 mm, 150 mm ▪ Midsection Diameters: 16 mm, 18 mm, 20 mm, 22 mm ▪ Dumbbell Diameters: 24 mm, 26 mm, 28 mm ▪ Coverage: Silicone Full Covered, Silicone Both Bare ▪ Radiopaque Markers: 8 platinum-iridium markers and 2 316L stainless steel markers ▪ Suture material: Nylon	**Substantially Equivalent:** • Dimensionally the same • General design is the same • Only the suture material has changed from Nylon to Polyester • Performance testing, biocompatibility testing, and shelf life testing demonstrate that the change in suture material does not affect safety or effectiveness of the device. Thus, the stent with the modified suture material is substantially equivalent to the predicate device.

	Subject Device	Predicate Device K080782, K240522	Comments
Design (Introducer)	**Niti-S Esophageal Stent** OTW (Over-The-Wire) type Stent Delivery System  Co-axial tube type Usable Length: 70cm Diameter: 16 Fr (5.3mm), 20 Fr (6.7mm) **Esophageal TTS Stent** TTS (Through-The-Scope) type Stent Delivery System  Co-axial tube type Usable Length: 180 and 220cm Diameter: 10.5 Fr (3.5mm)	**Niti-S Esophageal Stent** (K080782) OTW (Over-The-Wire) type Stent Delivery System  Co-axial tube type Usable Length: 70cm Diameter: 16 Fr (5.3mm), 20 Fr (6.7mm) **Esophageal TTS Stent** (K240522) TTS (Through-The-Scope) type Stent Delivery System  Co-axial tube type Usable Length: 180 and 220cm Diameter: 10.5 Fr (3.5mm)	Identical
Single Use	Yes	Yes	Identical
Sterile	EO Sterilization	EO Sterilization	Identical
Method of Placement	OTW (Over-The-Wire), TTS (Through-The-Scope)	OTW (Over-The-Wire), TTS (Through-The-Scope)	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 per ISO 10993-1 and FDA Guidance was performed to demonstrate the biological safety of the subject stents with the new polyester suture material.

Stent materials are considered implants in contact with tissue for > 30 days.

Table 2 outlines the testing conducted.

Table 2: Biocompatibility Testing Conducted

Test	Standard
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>
90-Day Subchronic Systemic Toxicity Rats	ISO 10993-11: 2017
In Vitro Mammalian Chromosomal Aberration (Genotoxicity) Chinese hamster lung cell line (CHL)	ISO 10993-3: 2015 ISO/TR 10993-33: 2015
Bacterial Reverse Mutation (Genotoxicity)	ISO 10993-3: 2015 ISO/TR 10993-33: 2015
4-Week Subcutaneous Implantation Testing Rats	ISO 10993-6: 2018
13-Week Subcutaneous Implantation Testing Rats	ISO 10993-6: 2018
Chemical Characterization Exhaustive extraction	ISO 10993-18:2020

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:

- Shelf-life testing
- Tensile testing

10. CONCLUSION

Based on the non-clinical performance and biocompatibility testing, the Esophageal TTS Stents and Niti-S Esophageal Stents are as safe and effective as the predicate devices and support a determination of substantial equivalence.