October 8, 2021

Taewoong Medical Co., Ltd
℅ Jennifer Moyer
Consultant, Medical Devices
Biologics Consulting Group, Inc.
1555 King Street, Suite 300
Alexandria, VA 22314

Re: K211706
Trade/Device Name: Esophageal TTS Stent
Regulation Number: 21 CFR 878.3610
Regulation Name: Esophageal Prosthesis
Regulatory Class: Class II
Product Code: ESW
Dated: June 1, 2021
Received: June 3, 2021

Dear Jennifer Moyer:

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K211706

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.

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.

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Esophageal TTS Stent is provided below.

1. SUBMITTER

Applicant: Taewoong Medical Co., Ltd.
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Submission Correspondent: Jennifer Moyer
Consultant, Medical Devices
Biologics Consulting Group, Inc.
Phone: (571) 279-5811
Email: jmoyer@biologicsconsulting.com

Date Prepared: August 24, 2021

2. DEVICE

Device Trade Name:	Esophageal TTS Stent
Device Common Name:	Esophageal Stent
Classification Name	878.3610, Prosthesis, Esophageal
Regulatory Class:	Class II
Product Code:	ESW

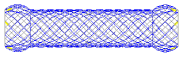
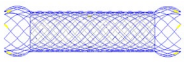
3. PREDICATE DEVICE

Primary Predicate Device:	K113551, Taewoong Esophageal TTS Stent
Additional Predicate Device:	K123205, Taewoong Esophageal TTS Stent
Reference Device:	K180144, Boston Scientific Agile Esophageal Stent System
Reference Device:	K200860, M.I. Tech HANAROSTENT Esophagus TTS (CCC) and HANAROSTENT Esophagus TTS (NCN)

4. DEVICE DESCRIPTION

The Esophageal TTS Stent consists of the implantable metallic stent and introducer system.

The stent is made of Nitinol wire. It is a flexible, fine mesh tubular prosthesis that has 10 radiopaque markers; 4 in each end and 2 in the center. It has a body diameter of 18, 20 and 22mm, and a total length from 60 to 150mm. The surface of the body portion of the stent is covered with silicone. The Esophageal TTS Stent is provided in two configurations, either fully covered with silicone or with both heads not covered in silicone (bare).

Type	Shape	Model Numbers*
Full Covered Type		ESTxxyyF
Both Bare Type		ESTxxyyB
*E- Esophageal Stent, S- Silicone Cover, T- TTS xx-diameter(mm), yy-length(cm), F-Full Covered, B-Both ends bared		

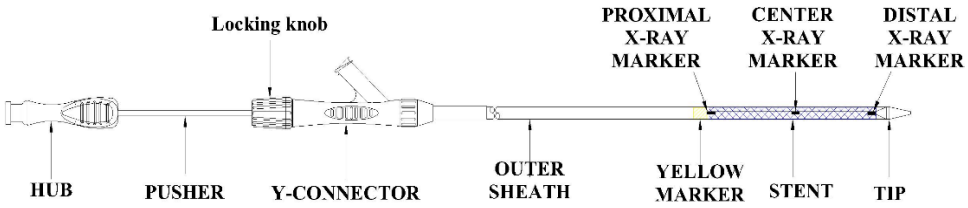


Figure 1: Introducer

The introducer system accepts a 0.035 in (0.89 mm) or 0.038 in (0.97 mm) guidewire. The stent introducer system is passed over the guidewire and through an endoscope into the esophagus. The stent may be positioned appropriately using the X-ray markers for guidance under fluoroscopy.

5. INTENDED USE/INDICATIONS FOR USE

For use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors.

6. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

Subject Device Indication for Use: *For use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors.*

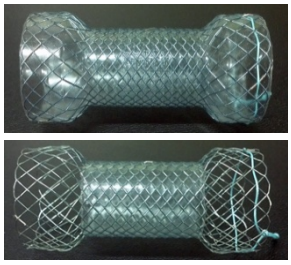
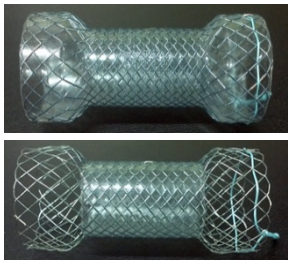
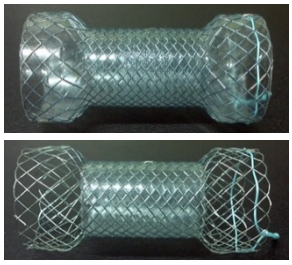
Primary Predicate Device (Taewoong Esophageal TTS Stent: K113551) Indication for Use: *For use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors.*

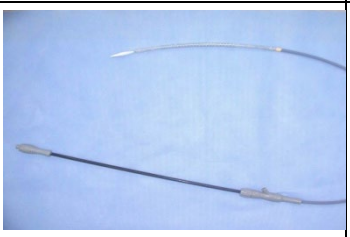
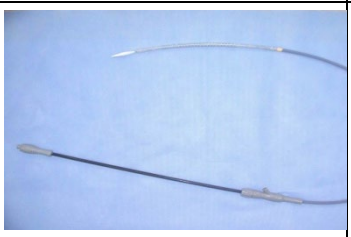
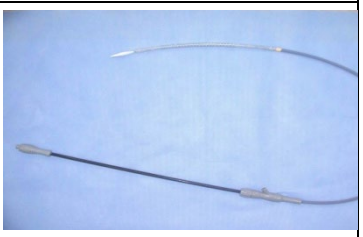
Additional Predicate Device (Taewoong Esophageal TTS Stent: K123205) Indication for Use: *For use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors.*

Technological Comparisons

Table 1 below compares the key technological feature of the subject devices to the primary predicate device (Taewoong Esophageal TTS Stent: K113551) and the additional predicate (Taewoong Esophageal TTS Stent: K123205).

Table 1: Technological Comparison – Predicate Devices

	Proposed Device	**Primary Predicate Device**	**Additional Predicate**
510(k) Number	TBD	K113551	K123205
Applicant	Taewoong Medical Co., Ltd.	Taewoong Medical Co., Ltd.	Taewoong Medical Co., Ltd.
Device Name	Esophageal TTS Stent	Esophageal TTS Stent	Esophageal TTS Stent
Classification Regulation	878.3610	878.3610	878.3610
Product Code	ESW	ESW	ESW
Indications for Use	For use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors.	For use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors.	For use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors.
Design (Stent)	 Nitinol wire Diamond shape Length; 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	 Nitinol wire Diamond shape Length; 60, 80, 100, 120, 140, 150 mm Body Diameter/Head Diameter; 18mm/26mm Coverage : · Silicone Full Covered · Silicone Both Bare Radiopaque Markers: 8 Pt/Ir, 2 STS 316L	 Nitinol wire Diamond shape Length; 60, 80, 100, 120, 140, 150 mm Body Diameter/Head Diameter; 20mm/26mm Coverage : · Silicone Full Covered · Silicone Both Bare Radiopaque Markers: 8 Pt/Ir, 2 STS 316L

	Proposed Device	Primary Predicate Device	Additional Predicate
Design (Introducer)	 Co-axial tube type Usable Length; · 180cm (for diameter 22mm stent) · 220cm (for diameter 18, 20 & 22 mm stent) Diameter; 10.5 Fr (3.5mm)	 Co-axial tube type Usable Length; · 180cm (for diameter 18mm stent) Diameter; 10.5 Fr (3.5mm)	 Co-axial tube type Usable Length; · 180cm (for diameter 18mm stent) Diameter; 10.5 Fr (3.5mm)
Single Use	Yes	Yes	Yes
Sterile	EO Sterilization	EO Sterilization	EO Sterilization
Method of Placement	Endoscopic	Endoscopic	Endoscopic
Method of Deployment	Release by pulling outer sheath	Release by pulling outer sheath	Release by pulling outer sheath
Materials	Stent – Nitinol, Pt/Ir, STS316L Cover – Silicone Introducer – Teflon, PE, ABS	Stent – Nitinol, Pt/Ir, STS316L Cover – Silicone Introducer – Teflon, PE, ABS	Stent – Nitinol, Pt/Ir, STS316L Cover – Silicone Introducer – Teflon, PE, ABS

7. PERFORMANCE DATA

Biocompatibility Testing

The Esophageal TTS Stent was evaluated according to the FDA's guidance "Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluating and testing within a risk management process" and it has been determined that no additional biocompatibility testing is required due to the device modification described in this submission.

Electrical safety and electromagnetic compatibility (EMC)

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

Software Verification and Validation Testing

Not applicable. The device contains no software.

Bench Testing

To establish the substantial equivalence of the Esophageal TTS Stent, bench testing was conducted on both the 22mm diameter size and the 220cm length to validate the performance of the device. The following tests were conducted:

- Deployment Test,
- Deployment Force Test,
- Expansion Force Test,
- Compression Force Test,
- Dimensional Test,
- Tensile Strength Test (Introducer System),
- Corrosion Test.

The following tests were also conducted:

- Packaging Adhesive Force Test,
- MR Compatibility.

The results of the bench testing show that the subject device meets its specifications and is substantially equivalent to the predicate and reference devices.

Animal Testing

Not applicable. Animal studies are not necessary to establish the substantial equivalence of this device.

Clinical Data

Not applicable. Clinical studies are not necessary to establish the substantial equivalence of this device.

8. CONCLUSION

Performance testing was conducted on all key performance attributes of the device. All samples met their acceptance criteria, demonstrating that when manufactured to specification, the device functions as intended and can be found substantially equivalent to the predicate device.