June 22, 2022

Taewoong Medical Co., Ltd.
% Matthew Krueger
Senior Consultant, Medical Devices
Biologics Consulting Group, Inc.
1555 King Street, Suite 300
Alexandria, VA 22314

Re: K221482
Trade/Device Name: Esophageal TTS Stent
Regulation Number: 21 CFR 878.3610
Regulation Name: Esophageal Prosthesis
Regulatory Class: Class II
Product Code: ESW
Dated: May 19, 2022
Received: May 23, 2022

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 (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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K221482

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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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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Biologics Consulting Group, Inc.
Phone: (667) 352-2578
Email: mkrueger@biologicsconsulting.com

Date Prepared: June 22, 2022

## 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 AND REFERENCE DEVICES

### 3.1. Predicate Devices

K211706: Taewoong Esophageal TTS Stent

K123205: Taewoong Esophageal TTS Stent

K113551: Taewoong Esophageal TTS Stent

### 3.2. Reference Device

K200860: HANAROSTENT Esophagus TTS (CCC) and HANAROSTENT Esophagus TTS (NCN)

# 4. DEVICE DESCRIPTION

The Esophageal TTS Stents that are the subject of this 510(k) are identical to the devices cleared in K211706, K123205, and K113551, with the exception of a modification to the Indications for Use statement. The Esophageal TTS Stents consists 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.

# 5. INTENDED USE/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.

# 6. SUBSTANTIAL EQUIVALENCE

## Comparison of Indications

**Table 1: Indications for Use Comparison**

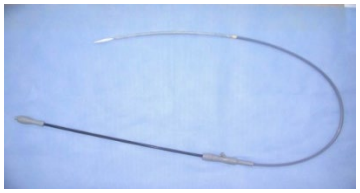
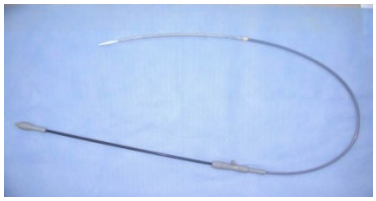
| Subject Device | Predicate Device (K211706) | Explanation of Differences |
|---|---|---|
| The Esophageal TTS Stent is intended for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors and occlusion of concurrent esophageal fistulas. | The Esophageal TTS Stent is intended for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors. | Similar to predicate and is nearly identical to the reference device K200860 which used the Taewoong TTS Stent (K123205) as its predicate.<br>This addition to the Indications for Use does not affect the safety and efficacy of the device because the device design and intended use is identical to the predicate. |

## Technological Comparisons

The table below compares the key technological feature of the subject devices to the predicate device (Taewoong Esophageal TTS Stent, K211706).

**Table 2: Technological Comparison**

| | **Subject Device** | **Predicate K211706 (K123205 and K113551)** |
|---|---|---|
| Device Name | Esophageal TTS Stent | Esophageal TTS Stent |
| Common Name | Esophageal Stent | Esophageal Stent |
| Manufacturer | Taewoong Medical Co., Ltd | Taewoong Medical Co., Ltd |
| Classification Regulation | 878.3610 | 878.3610 |
| Product Code | ESW | ESW |
| 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. |
| Design (Stents) |  <br>Full Covered Stent<br>  <br>Both Bare Stent<br>Nitinol wire in diamond shape<br>Lengths; 60, 80, 100, 120, 140, 150mm<br>Body Diameter/Head Diameter:<br>· 18mm/26mm<br>· 20mm/26mm<br>· 22mm/28mm<br>Coverage:<br>· Silicone Full Covered<br>· Silicone Both Bare<br>Radiopaque Markers: 8 Pt/Ir, 2 STS 316L |  <br>Full Covered Stent<br>  <br>Both Bare Stent<br>Nitinol wire in diamond shape<br>Lengths; 60, 80, 100, 120, 140, 150mm<br>Body Diameter/Head Diameter:<br>· 18mm/26mm<br>· 20mm/26mm<br>· 22mm/28mm<br>Coverage:<br>· Silicone Full Covered<br>· Silicone Both Bare<br>Radiopaque Markers: 8 Pt/Ir, 2 STS 316L |

| | Subject Device | Predicate<br>K211706<br>(K123205 and K113551) |
|---|---|---|
| Design (Introducer) |  <br>Co-axial tube type<br>Usable Length:<br>· 180cm (for diameter 22mm stent)<br>· 220cm (for diameter 18, 20 & 22 mm stent)<br>Diameter; 10.5 Fr (3.5mm) |  <br>Co-axial tube type<br>Usable Length;<br>· 180cm (for diameter 22mm stent)<br>· 220cm (for diameter 18, 20 & 22 mm stent)<br>Diameter; 10.5 Fr (3.5mm) |
| Single Use | Yes | Yes |
| Sterile | EO Sterilization | EO Sterilization |
| Method of Placement | Endoscopic | Endoscopic |
| Method of Deployment | Release by pulling outer sheath | Release by pulling outer sheath |
| Materials | Stent – Nitinol, Pt/Ir, STS316L<br>Cover – Silicone<br>Introducer – Teflon, PE, ABS | Stent – Nitinol, Pt/Ir, STS316L<br>Cover – Silicone<br>Introducer – Teflon, PE, ABS |

# 7. PERFORMANCE DATA

## Biocompatibility Testing

The subject device in its final finished form is identical to the Esophageal TTS Stent cleared in K211706, K123205, and K113551, in formulation, processing, sterilization, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents).

Therefore, no additional biocompatibility information is required to establish substantial equivalence.

## 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

No design modifications have been made to the cleared Esophageal TTS Stent. The only change is to the Indications for Use. An assessment of the change was performed, and it was determined that the modified Indications for Use do not introduce any new risks. Thus, testing previously performed for the Esophageal TTS Stent is appropriate and sufficient for the modified Indications for Use. The testing on the Esophageal TTS Stent is consistent with the testing performed on the reference device which uses this identical Indications for Use statement. Therefore, no additional performance data is required.

## 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

Based on the modified Indications for Use, the technological characteristics and materials of construction, the Esophageal TTS Stent can be found substantially equivalent to the identified predicate device.