March 31, 2025

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

Re: K250663
Trade/Device Name: Niti-S Duodenal Comfort Stent
Niti-S Colonic Comfort Stent
Regulation Number: 21 CFR 878.3610
Regulation Name: Esophageal Prosthesis
Regulatory Class: Class II
Product Code: MUM, MQR
Dated: March 5, 2025
Received: March 5, 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,

Anthony Lee -S

Anthony Lee, Ph.D., M.B.A.
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)*

K250663

Device Name

Niti-S Duodenal Comfort Stent, Niti-S Colonic Comfort Stent

Indications for Use *(Describe)*

Niti-S Duodenal Comfort Stent is indicated for the palliative treatment of pyloric or duodenal obstructions caused by malignant neoplasms.

Niti-S Colonic Comfort Stent is indicated for the palliative treatment of colorectal strictures produced by malignant neoplasms and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.

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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Phone:	+82 70 4649 1543
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2. CORRESPONDENT INFORMATION

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

3. DATE PREPARED: MARCH 4, 2025

4. DEVICE INFORMATION

Device Name:	Niti-S Duodenal Comfort Stent Niti-S Colonic Comfort Stent
Common Name:	Duodenal stent; colonic stent
Regulation Number:	21 CFR 878.3610
Regulation Name:	Esophageal Prosthesis
Product Code:	MUM (Niti-S Duodenal Comfort Stent) MQR (Niti-S Colonic Comfort Stent)
Regulatory Class:	Class II

5. PREDICATE DEVICE INFORMATION

Primary Predicate Device Name:	Niti-S Duodenal Comfort Stent; Niti-S Colonic Comfort Stent
510(k) Number:	K223067
Manufacturer:	Taewoong Medical

Reference Device Name:	Esophageal TTS Stent
510(k) Number:	K240522
Manufacturer:	Taewoong Medical

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

6. DEVICE DESCRIPTION

The Niti-S Duodenal Comfort Stent and Niti-S Colonic Comfort Stent consist of an implantable metallic stent and an introducer system.

The stent is made of nitinol wire and is designed as a flexible, fine mesh tubular prosthesis with several radiopaque markers. The Niti-S Duodenal Comfort Stent has a diameter of 22 mm, while the Niti-S Colonic Comfort Stent is available in diameters of 22 mm and 24 mm. Both stent types are available in lengths of 60 mm, 80 mm, 100 mm, and 120 mm.

The stent delivery system accommodates a 0.035 in (0.89 mm) guidewire. It is advanced over the guidewire and passed through an endoscope into the duodenum or colon. Fluoroscopy is recommended to ensure accurate device placement.

7. INDICATIONS FOR USE

Niti-S Duodenal Comfort Stent is indicated for the palliative treatment of pyloric or duodenal obstructions caused by malignant neoplasms.

Niti-S Colonic Comfort Stent is indicated for the palliative treatment of colorectal strictures produced by malignant neoplasms and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.

8. COMPARISON OF INTENDED USE

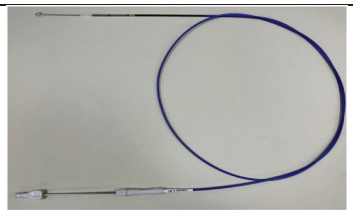
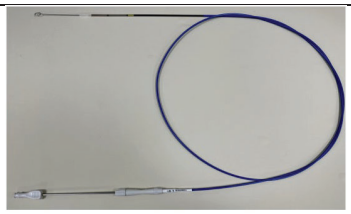
The Indications for Use are for the Niti-S Duodenal Comfort Stent and Niti-S Colonic Comfort Stent are unchanged from the cleared predicate devise (K223067). The purpose of this 510(k) is to align the design of the subject stent delivery systems (SDSs) with those of the Esophageal TTS Stent (K240522). These changes included slight component modifications and some material changes. The principle of operation of the updated Niti-S Duodenal Comfort Stent and Niti-S Colonic Comfort Stent SDSs remains unchanged. Fluoroscopic and/or endoscopic guidance is still used for SDS positioning and the stent deployment procedure is the same overall.

9. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE REFERENCE DEVICE

The table below compares the new Niti-S Duodenal and Colonic Comfort SDSs that are being proposed for use with the subject device and compares it to the Esophageal TTS SDSs. The new

subject SDSs are based off the design of the Esophageal TTS SDSs and is largely identical other than the differences noted below.

Table 1: Niti-S Duodenal Comfort Stent and Niti-S Colonic Comfort Stent SDS Technological Comparison to Reference Device

	Subject Device-	**Reference Device** K240522
Trade/Device Name	Niti-S Duodenal Comfort Stent Niti-S Colonic Comfort Stent	Esophageal TTS Stent
Regulation Number	21 CFR 878.3610	21 CFR 878.3610
Expansion method	The stent is loaded into the distal part of the delivery device and expanded in the body by pulling the outer sheath of the delivery device. The stent is made of self-expanding nitinol.	The stent is loaded into the distal part of the delivery device and expanded in the body by pulling the outer sheath of the delivery device. The stent is made of self-expanding nitinol.
Method of introduction	Endoscopic	Endoscopic
Sterility	EO Sterilization	EO Sterilization
Delivery system photo	 Co-axial tube type	 Co-axial tube type
Delivery system length	220 cm (endoscopic)	180 cm (endoscopic) 220 cm (endoscopic)
Delivery system profile	10 Fr (3.3 mm)	10.5 Fr (3.5 mm)
Guidewire	0.035 in (0.89 mm)	0.035 in (0.89 mm) 0.038 in (0.97 mm)

10. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Biocompatibility Testing

The stent material of the subject device is identical to that of the Niti-S Duodenal Comfort Stent and Niti-S Colonic Comfort Stent cleared in K223067, including its formulation, processing, and sterilization, with no additional chemicals (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents) introduced.

Similarly, the SDS material of the subject device is identical to the Esophageal TTS Stent cleared in K240522 by Taewoong Medical, including its formulation, processing, and sterilization, with no additional chemicals added.

Therefore, additional biocompatibility testing for the Stent Delivery System is not required.

Electrical Safety

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

Electromagnetic Compatibility (EMC)

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

Software

Not applicable. The subject device contains no software.

Performance Testing

Additional performance testing was conducted to demonstrate that the device meets its design requirements and performs as intended. Samples were aged to reflect the stent and SDS shelf-life and the following tests/analyses were performed.

- Packaging strength and dye penetration
- Sterility verification
- Deployment accuracy test
- Deployment force test
- Dimensional test
- Tensile strength test (SDS)
- Trackability and visualization test
- Repositioning force test

11. CONCLUSION

The results of the performance testing described above demonstrate that the Niti-S Duodenal Comfort Stent and Niti-S Colonic Comfort Stent are as safe and effective as the predicate device and supports a determination of substantial equivalence.