December 29, 2025

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

Re: K251123
Trade/Device Name: Niti-S Biliary Stent; Niti-S Biliary Slim M Stent
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter And Accessories
Regulatory Class: Class II
Product Code: FGE
Dated: December 1, 2025
Received: December 1, 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 and the limitations described below. 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.

The OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the device's labeling:

1. The safety and effectiveness of this device for use in the vascular system has not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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,

GLENN B. BELL -S

for Michael J. Hoffmann
Director
OHT3: 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)*

K251123

Device Name

Niti-S Biliary Stent ;
Niti-S Biliary Slim M Stent

Indications for Use *(Describe)*

Niti-S Biliary Stent:
The Niti-S Biliary Stent is indicated for the palliation of malignant strictures in the biliary tree.

Niti-S Biliary Slim M Stent:
The Niti-S Biliary Slim M Stent is indicated for the palliation of malignant strictures in the biliary tree.

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.

1. SUBMITTER INFORMATION

Applicant:	Taewoong Medical Co., Ltd.
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2. CORRESPONDENT INFORMATION

Contact:	Matthew Krueger
Title:	Principal Consultant
Firm:	Biologics Consulting Group 100 Daingerfield Rd, Suite 101 Alexandria, VA 22314
Phone:	(667) 352-2578
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3. DATE PREPARED: DECEMBER 16, 2025

4. DEVICE INFORMATION

Device Name:	Niti-S Biliary Stent & Niti-S Biliary Slim M Stent
Common Name:	Biliary catheter and accessories
Regulation Number:	21 CFR 876.5010
Regulation Name:	Biliary catheter and accessories
Product Code:	FGE
Regulatory Class:	Class II

5. PREDICATE DEVICE INFORMATION

Primary Predicate Device Name:	Niti-S Biliary Slim M Stent
510(k) Number:	K221071
Manufacturer:	Taewoong Medical Co., Ltd.

Secondary Predicate Device Name:	Niti-S Biliary Stent
510(k) Number:	K073667
Manufacturer:	Taewoong Medical Co., Ltd.
Reference Device Name:	Esophageal TTS Stent
510(k) Number:	K240522
Manufacturer:	Taewoong Medical Co., Ltd.
Additional Reference Device Name:	Niti-S Duodenal Comfort Stent, Niti-S Colonic Comfort Stent
510(k) Number:	K250663
Manufacturer:	Taewoong Medical Co., Ltd.

6. DEVICE DESCRIPTION

The Niti-S Biliary Stent consists of an implantable metallic stent and a disposable, flexible Stent Delivery System for placement of the stent. The stent is a flexible and expandable tubular device made of Nitinol wire. Two Nitinol wires are woven in a hook-type design. The stent design is identical to the predicate device cleared in K073667.

The Stent Delivery System is a disposable system for the delivery and deployment of the stent at the target position.

7. INDICATIONS FOR USE

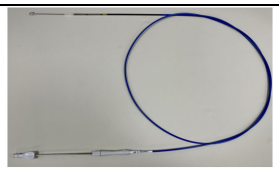
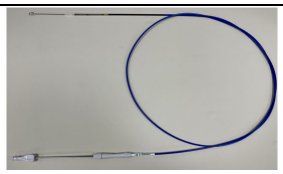
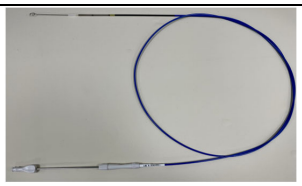
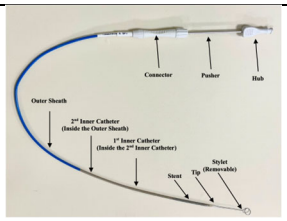
The Niti-S Biliary Stent is indicated for the palliation of malignant strictures in the biliary tree.

The Niti-S Biliary Slim M Stent is indicated for the palliation of malignant strictures in the biliary tree.

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

The Indications for Use are for the Niti-S Biliary Stent and Niti-S Biliary Slim M Stent are unchanged from the cleared predicate devises (K073667 and K221071). 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 Biliary Stent and Niti-S Biliary Slim M Stent SDSs remains unchanged. Fluoroscopic and/or endoscopic guidance is still used for SDS positioning and the stent deployment procedure is the same overall.

Table 1: Niti-S Biliary Stent and Niti-S Biliary Slim M Stent SDS Technological Comparison to Reference Device

	Subject Device **Niti-S Biliary Stent**	**Subject Device-** **Niti-S Biliary Slim M Stent**	**Reference Device** **Esophageal TTS Stent SDS** K240522
Trade/Device Name	Niti-S Biliary Stent	Niti-S Biliary Slim M Stent	Esophageal TTS Stent
Regulation Number	21 CFR 876.5010	21 CFR 876.5010	21 CFR 878.3610
Expansion method	The self-expanding Nitinol stent is pre-loaded into the distal part of the delivery system and is expanded in the body by pulling the outer sheath of the delivery device.	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 self-expanding Nitinol stent is pre-loaded into the distal part of the delivery system and is expanded in the body by pulling the outer sheath of the delivery device.
Method of introduction	Endoscopic, Percutaneous	Endoscopic	Endoscopic
Sterility	EO Sterilization	EO Sterilization	EO Sterilization
Delivery system photo	 Co-axial tube type (endoscopic)	 Co-axial tube type	 Co-axial tube type
Delivery system photo	 Co-axial tube type (percutaneous)	Not applicable.	Not applicable.
Delivery system length	180 cm (endoscopic), 50 cm (percutaneous)	180 cm (endoscopic)	180 cm (endoscopic), 220 cm (endoscopic)
Delivery system profile	8 Fr (2.7 mm)	6 Fr (2 mm)	10.5 Fr (3.5 mm)
Guidewire (in inches)	0.035 in	0.025 in	0.035 in (0.89 mm) 0.038 in (0.97 mm)

9. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Biocompatibility Testing

The stent materials of the subject devices are identical to those of the Niti-S Biliary Stent cleared in K073667 and the Niti-S Biliary Slim M Stent cleared in K221071, 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. The performance tests include:

- Packaging strength and dye penetration
- Sterility verification
- Delivery Force & Withdrawal Force
- Deployment Force
- Deployment Accuracy
- SDS Bonding Strength
- Crossing Profile
- Radiopacity evaluation

10. CONCLUSION

The results of the performance testing described above demonstrate that the Niti-S Biliary Stent and the Niti-S Biliary Slim M Stent perform equivalently as compared to the predicate and reference devices and supports a determination of substantial equivalence.