May 26, 2023

Taewoong Medical Co., Ltd
% Matthew Krueger
Senior Consultant
Biologics Consulting Group, Inc.
100 Daingerfield Road, Suite 400
Alexandria, VA 23314

Re: K223626
Trade/Device Name: Niti-S Biliary Speed D Stent
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: April 24, 2023
Received: April 25, 2023

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 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 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.

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 Warnings section of 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.

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,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Office Director
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)*
K223626

Device Name
Niti-S Biliary Speed D Stent

Indications for Use *(Describe)*
The Niti-S Biliary Speed D 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92), the 510(k) Summary for the Niti-S Biliary Speed D Stent is provided below.

1. SUBMITTER

Applicant: Taewoong Medical Co., Ltd.
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Phone: (571) 777-9505
Email: mkrueger@biologicsconsulting.com

Date Prepared: May 22, 2023

2. DEVICE

Device Trade Name:	Niti-S Biliary Speed D Stent
Device Common Name:	Biliary catheter and accessories
Classification Name	21 CFR 876.5010, Biliary Catheter & Accessories
Regulatory Class:	Class II
Product Code:	FGE

3. PREDICATE DEVICE

Predicate Device: K073667 – Taewoong Medical Niti-S Biliary Stent

4. DEVICE DESCRIPTION

The Niti-S Biliary Speed D 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.

5. INDICATIONS FOR USE

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

6. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

Predicate Device Indications for Use

Indicated for the palliation of malignant strictures in the biliary tree.

Subject Device Indications for Use

Indicated for the palliation of malignant strictures in the biliary tree.

Discussion of Similarities and Differences

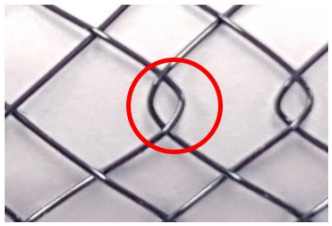
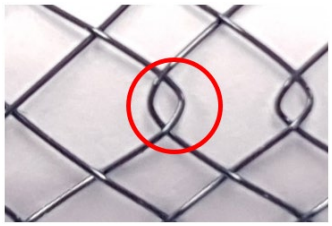
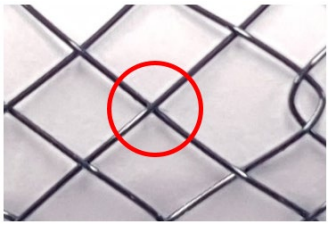
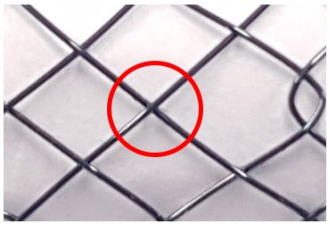
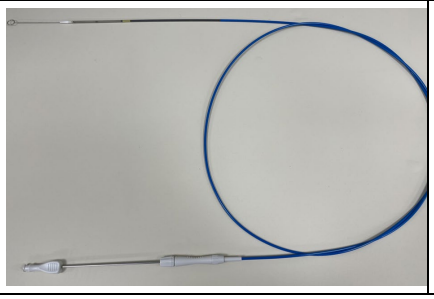
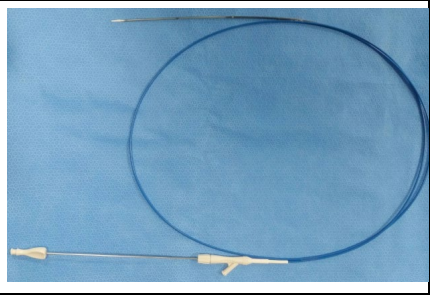
The Indications for Use of the predicate and subject devices are identical.

Technological Comparisons

The table below compares the key technological feature of the subject devices to the predicate device (K073667 – Taewoong Medical Niti-S Biliary Stent).

Table 1: Technological Comparison

Characteristic	Subject Device	Predicate Device
510(k) number	TBD	K073667
Trade/Device Name	Niti-S Biliary Speed D Stent	Niti-S Biliary Stent
Manufacturer	Taewoong Medical Co., Ltd.	Taewoong Medical Co., Ltd.
Regulation Number	21 CFR 876.5010	21 CFR 876.5010
Indication for use statement	The Niti-S Biliary Speed D Stent is indicated for the palliation of malignant strictures in the biliary tree.	The Niti-S Biliary Stent is indicated for the palliation of malignant strictures in the biliary tree.

Characteristic	Subject Device	Predicate Device
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 loaded into the distal part of the delivery device, and expanded in the body by pulling the outer sheath of the delivery device.
Method of introduction	Endoscopic	Endoscopic, Percutaneous
Sterility	EO Sterilization	EO Sterilization
Stent material	Nitinol, Pt/Ir, STS316L	Nitinol, Pt/Ir, STS316L
Stent lengths	40 mm, 50 mm, 60 mm, 70 mm, 80 mm, 90 mm, 100 mm, 120 mm	40 mm, 50 mm, 60 mm, 70 mm, 80 mm, 90 mm, 100 mm, 120 mm
Stent diameters	8 mm, 10 mm	8 mm, 10 mm
Stent geometry	– Hook shape – Straight ends – 10 radiopaque markers	– Hook shape – Straight ends – 10 radiopaque markers
Stent photo		
Hook Structure		
Cross Structure		
Cell width	App. 2.57 mm	App. 2.57 mm
Cell height	App. 2.02 mm	App. 2.02 mm
Overall Cell area	App. 2.60 mm²	App. 2.60 mm²
Delivery system photo		

Characteristic	Subject Device	Predicate Device
Delivery system material	PC/ABS, STS304, PTFE, PEBAX, Nylon, Tungsten, Pad printing ink, etc.	PC/ABS, STS304, PTFE, PEBAX, Nylon, Tungsten, etc.
Delivery system length	180 cm (Endoscopic)	180 cm (Endoscopic), 50 cm (Percutaneous)
Delivery system profile	8.5 Fr (2.8 mm)	8 Fr (2.7 mm)
Guidewire (in inches)	0.035	0.035

7. PERFORMANCE DATA

Sterility

The Niti-S Biliary Speed D Stent and stent delivery system (SDS) is provided as a sterile device sterilized using traditional ethylene oxide.

Table 2: Sterilization Cycle Parameters

Parameter	Levels
Sterilization Method	Ethylene oxide
Sterility validation method	Half-cycle method using ISO 11135:2014
Sterility Assurance Level	10^{-6}

Shelf Life and Shipping

Taewoong Medical performed the following shelf life and shipping testing to evaluate the Niti-S Biliary Speed D Stent.

The following tests were performed:

- ASTM 1980-21, *Standard Guide For Accelerated Aging Of Sterile Barrier Systems And Medical Device*s
- ASTM D4169-16, *Standard Practice For Performance Testing Of Shipping Containers And Systems*

Biocompatibility Testing

The stent material of the subject device is identical to the Niti-S Biliary Stent cleared in K073667 including the formulation, processing and sterilization, and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents).

The SDS material of the subject device is not identical to the Niti-S Biliary Stent cleared in K073667. Therefore, additional biocompatibility testing for the Stent Delivery System of the subject device was conducted in accordance with the ISO 10993 series to establish substantial equivalence.

The following testing was done:

- ISO 10993-5:2009 – Cytotoxicity
- ISO 10993-10:2010 – Irritation and skin sensitization

Electrical safety and 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 Verification and Validation Testing

Not applicable. The subject device contains no software of any type.

Bench Testing

Taewoong Medical performed the following non-clinical bench testing to evaluate the Niti-S Biliary Speed D Stent. Test samples were obtained from different manufacturing lots for all tests.

The following tests were performed on the stent:

- Pitting Corrosion Potential,
- Galvanic Corrosion,
- Dimensional Verification,
- Foreshortening,
- Stent Integrity,
- Radial Compression Force,
- Radial Outward Force,
- Radiopacity,
- Magnetic Resonance (MR) Safety

The following tests were performed on the Stent Delivery System (SDS):

- Delivery,
- Deployment,
- Withdrawal,
- SDS Bond Strength,
- Crossing Profile

The following test was performed on the packaged components:

- Shipping test

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 detailed comparison between the predicate device and the subject device, the performance testing, and conformance with applicable standards, the Niti-S Biliary Speed D Stent can be found substantially equivalent to the predicate device.