



June 9, 2022

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

Re: K221071  
Trade/Device Name: Niti-S Biliary Slim M Stent  
Regulation Number: 21 CFR§ 876.5010  
Regulation Name: Biliary Catheter and Accessories  
Regulatory Class: II  
Product Code: FGE  
Dated: April 7, 2022  
Received: April 12, 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 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

## Indications for Use

510(k) Number (if known)  
K221071

Device Name  
Niti-S Biliary Slim M Stent

Indications for Use (Describe)

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.

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:

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*"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."*

## 510(k) Summary

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

### 1. SUBMITTER

Applicant: Taewoong Medical Co., Ltd.  
14 Gojeong-ro, Wolgot-myeon, Gimpo-si, Gyeonggi-do, Korea, 10022  
TEL: +82-31-996-0641  
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Contact: Matthew Krueger  
Senior Consultant, Medical Devices  
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Submission Correspondent: Matthew Krueger  
Senior Consultant, Medical Devices  
Biologics Consulting Group, Inc.  
Phone: (571) 777-9505  
Email: mkrueger@biologicsconsulting.com

Date Prepared: 05/26/2022

### 2. DEVICE

Device Trade Name: Niti-S Biliary Slim M 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

Primary Predicate Device: Taewoong Medical Niti-S Biliary Stent (K073667)  
Secondary Predicate Device: M.I.Tech Co., Ltd., HANAROSTENT Benefit™ Biliary (NNN) (K202973)

### 4. DEVICE DESCRIPTION

The Niti-S Biliary Slim M Stent consists of the implantable metallic stent and introducer system.

510(k) Summary

The stent is made of Nitinol wire. It is a flexible, fine mesh tubular prosthesis and it has 7 radiopaque markers; 3 in each end and 1 in the center. It has a diameter of 6 or 8 mm and the length ranges from 40 to 120mm.

**5. INTENDED USE/INDICATIONS FOR USE**

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

**6. SUBSTANTIAL EQUIVALENCE**

**Comparison of Indications**

Subject Device	Primary Predicate (K073667)	Secondary Predicate (K202973)
Indicated for the palliation of malignant strictures in the biliary tree.	Indicated for the palliation of malignant strictures in the biliary tree.	Indicated for the palliation of malignant strictures in the biliary tree.

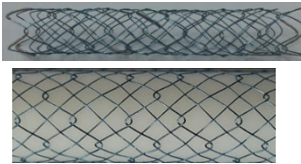
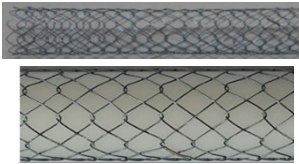



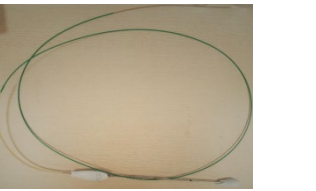
**Technological Comparisons**

The table below compares the key technological feature of the subject devices to the primary predicate device (Niti-S Biliary Stent, K073667) and the secondary predicate (HANAROSTENT Benefit™ Biliary (NNN), K202973).

**Table 1: Technological Comparison**

Characteristic	Subject Device	Primary Predicate Device	Secondary Predicate Device
510(k) number	TBD	K073667	K202973
Trade/Device Name	Niti-S Biliary Slim M Stent	Niti-S Biliary Stent	HANAROSTENT Benefit™ Biliary (NNN)
Manufacturer	Taewoong Medical Co., Ltd.	Taewoong Medical Co., Ltd.	M.I. Tech Co., Ltd.
Regulation Number	21 CFR 876.5010	21 CFR 876.5010	21 CFR 876.5010
Indication for use statement	The Niti-S Biliary Slim M 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.	The HANAROSTENT® Benefit™ Biliary (NNN) is indicated for the palliation of malignant strictures in the biliary tree.
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.	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.

510(k) Summary

Characteristic	Subject Device	Primary Predicate Device	Secondary Predicate Device
Method of introduction	Endoscopic	Endoscopic, Percutaneous	Endoscopic, Percutaneous
Sterility	EO Sterilization	EO Sterilization	EO Sterilization
Stent photo			
Stent material	Nitinol, Pt/Ir, STS316L	Nitinol, Pt/Ir, STS316L	Nitinol, Gold
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	40 mm, 120 mm
Stent diameters	6 mm, 8 mm	8 mm, 10 mm	6 mm, 8 mm
Stent geometry	<ul style="list-style-type: none"> <li>- Cross &amp; hook shape</li> <li>- Straight ends</li> <li>- 9 radiopaque markers</li> </ul>	<ul style="list-style-type: none"> <li>- Hook shape</li> <li>- Straight ends</li> <li>- 10 radiopaque markers</li> </ul>	<ul style="list-style-type: none"> <li>- Cross &amp; hook shape</li> <li>- Straight ends</li> <li>- 9 radiopaque markers</li> </ul>
Delivery system photo			
Delivery system material	Teflon, PE, ABS	Teflon, PE, ABS	Polymeric materials
Delivery system length	180 cm (Endoscopic)	180 cm (Endoscopic), 50 cm (Percutaneous)	180 cm (Endoscopic), 60 cm (Percutaneous)
Delivery system profile	6 Fr	8 Fr	5.9 Fr
Guidewire (in inches)	0.025	0.035	0.025

**7. PERFORAMNCE DATA**

**Biocompatibility Testing**

The material of the subject device in its final finished form, including the stent and delivery system, is identical to the Taewoong Medical Co. Ltd. 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).

### **Electrical safety and electromagnetic compatibility (EMC)**

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

### **Software Verification and Validation Testing**

Not applicable. It contains no software of any type.

### **Bench Testing**

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 environment.

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 primary predicate device, secondary predicate device and the subject device, the performance testing and conformance with applicable standards, the Niti-S Biliary Slim M Stent can be found substantially equivalent to the predicate device.