June 14, 2023

Taewoong Medical Co., Ltd.
% Daniel Dillon
Senior Regulatory Specialist
MED Institute
1330 Win Hentschel Boulevard
Suite 100
West Lafayette, Indiana 47906

Re: K223067
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: II
Product Code: MUM (Niti-S Duodenal Comfort Stent)
MQR (Niti-S Colonic Comfort Stent)
Dated: May 9, 2023
Received: May 10, 2023

Dear Daniel Dillon:

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,

Nicholas Clay -S

for Glenn Bell, Ph.D.
Division 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)*
K223067

Device Name
Niti-S Duodenal Comfort Stent; Niti-S Colonic Comfort Stent

Indications for Use *(Describe)*
The Niti-S Duodenal Comfort Stent is indicated for the palliative treatment of pyloric or duodenal obstructions caused by malignant neoplasms.

The 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.

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1. SUBMITTER

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Date Prepared: May 9, 2023

2. DEVICE

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

3. PREDICATE DEVICES

K183616	M.I. Tech Co., Ltd, HANAROSTENT LowAx™ Duodenum/Pylorus
K190141	M.I. Tech Co., Ltd, HANAROSTENT LowAx™ Colon/Rectum

4. DEVICE DESCRIPTION

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

The stent is made of nitinol wire. It is a flexible, fine mesh tubular prosthesis that has several radiopaque markers. The Niti-S Duodenal Comfort Stent has a diameter of 22 mm while the Niti-S Colonic Comfort Stent has diameters of 22 and 24 mm. They both have lengths of 60, 80, 100, and 120 mm.

The introducer system accepts a 0.035 in (0.89 mm) guidewire. The introducer system is passed over the guidewire and through an endoscope into the duodenum or colon. Use of fluoroscopy is recommended to ensure correct placement of the device.

5. INDICATIONS FOR USE

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

The 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.

6. SUBSTANTIAL EQUIVALENCE

The table below compares the key technological features of the subject devices to the predicate devices (M. I. Tech Co., Ltd, HANAROSTENT LowAx™ Colon/Rectum and HANAROSTENT LowAx™ Duodenum/Pylorus).

	Niti-S Duodenal Comfort Stent (Subject Device)	**HANAROSTENT LowAx™ Duodenum/Pylorus Stent (K183616)**	**Niti-S Colonic Comfort Stent (Subject Device)**	**HANAROSTENT LowAx™ Colon/Rectum Stent (K190141)**
Stent				
Main material	Nitinol wire	Nitinol wire	Nitinol wire	Nitinol wire
Design	Cross-and-hook weave using two wires; one head/flare	Cross-and-hook weave using two wires; one head/flare	Cross-and-hook weave using two wires; one head/flare	Cross-and-hook weave using two wires; one head/flare
Body Diameters/Head Diameters	22 mm/27 mm	22 mm/27 mm	· 22 mm/27 mm · 24 mm/29 mm	· 22 mm/27 mm · 25mm /30 mm
Lengths	60, 80, 100, 120 mm	60, 90, 120 mm	60, 80, 100, 120 mm	60, 90, 120 mm
Polymer cover?	No	No	No	No
Radiopaque Markers	11 Pt/Ir, 2 STS 316L	12 Gold	11 Pt/Ir, 2 STS 316L	12 Gold
Introducer				
Design	Co-axial tube	Co-axial tube	Co-axial tube	Co-axial tube
Method of placement and deployment	Endoscopic; release by pulling outer sheath	Endoscopic; release by pulling outer sheath	Endoscopic; release by pulling outer sheath	Endoscopic; release by pulling outer sheath
Diameter	10 Fr (3.3 mm)	10.2 Fr (3.4 mm)	10 Fr (3.3 mm)	10.2 Fr (3.4 mm)
Usable Length	220 cm	230 cm	220 cm	230 cm
Compatible guidewire	0.035″	0.035″	0.035″	0.035″

7. PERFORMANCE DATA

Sterility and Packaging Testing

The Niti-S Duodenal Comfort Stent and Niti-S Colonic Comfort Stent and introducer are provided as sterile devices. The sterilization method, validation method, and sterility assurance level are in accordance with ISO 11135:2014, “Sterilization of health-care products – Ethylene oxide – Requirement for the development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1(2018)]”.

Packaging was designed, tested, and validated in accordance with AAMI/ANSI/ISO 11607-1:2019, “Packaging for terminally sterilized medical devices – Part 1: Requirements for

materials, sterile barrier systems and packaging" and AAMI/ANSI/ISO 11607-2:2019, "Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes".

Biocompatibility Testing

The Niti-S Duodenal Comfort Stent and Niti-S Colonic Comfort Stent were evaluated according to the FDA's guidance "Use of InternationalStandard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluating and testing within a risk management process". The stent and introducer were evaluated for cytotoxicity, sensitization, and irritation/ intracutaneous reactivity effects. The stent was also evaluated for acute systemic toxicity, material-mediated pyrogenicity, subacute/subchronic toxicity, chronic toxicity, and implantation effects. The evaluation determined that the devices have an acceptable biocompatibility profile.

Bench Testing

To establish the substantial equivalence of both Niti-S Duodenal Comfort Stent and Niti-S Colonic Comfort Stent, bench testing was conducted to validate the performance of both devices. The following tests were conducted:

- Deployment Accuracy
- Deployment Force
- Expansion Force
- Compression Force
- Dimensional
- Tensile Strength
- Shipping
- Shelf-life
- Corrosion
- MR Compatibility
- Axial Force
- Trackability and Visualization
- Repositioning Force
- Radiopacity

The results of the bench testing show that the subject devices meet their specifications and are substantially equivalent to the predicate devices.

8. CONCLUSION

The subject devices have indications for use that are the same as the predicate devices and technological characteristics that are similar to the predicate devices. The performance data demonstrate that the subject devices meet their specification and do not raise new questions of

safety or effectiveness. These results support a determination of substantial equivalence of the subject devices to the predicate devices.