May 20, 2020

M.I. Tech Co., Ltd
% Beryl St. Jeanne, MS, RAC
Regulatory Consultant
Namsa
400 Highway 169 South Suite 500
Minneapolis, MN 55426

Re: K200860
Trade/Device Name: HANAROSTENT Esophagus TTS (CCC), HANAROSTENT Esophagus TTS (NCN)
Regulation Number: 21 CFR 878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: ESW
Dated: March 31, 2020
Received: April 1, 2020

Dear Beryl St. Jeanne:

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,

for
Shanil P. Haugen, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200860

Device Name
HANAROSTENT® Esophagus TTS (CCC); HANAROSTENT® Esophagus TTS (NCN)

Indications for Use *(Describe)*
The HANAROSTENT® Esophagus TTS (CCC) and HANAROSTENT® Esophagus TTS (NCN) are intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors, and occlusion of concurrent esophageal fistulas.

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."

M.I.Tech
www.mitech.co.kr

HEAD OFFICE
174, HABUK2-GIL, JINWI-MYEON, PYEONGTAEK-SI, GYEONGGI-DO,
17706, REPUBLIC OF KOREA
TEL +82 31 662 5645 FAX +82 31 662 5648

6 510(k) Summary

Preparation Date	March 31, 2020	
Submitter	M.I. Tech Co., Ltd. 174 Habuk 2-gil, Jinwi-myeon, Pyeongtaek-si, Gyeonggi-do 17706, Republic of Korea Phone: 82-31-662-5645 Fax: 82-31-662-5648	
Primary Contact	Inae Kim Medical Affairs Team Manager M.I. Tech Co., Ltd. 174 Habuk 2-gil, Jinwi-myeon, Pyeongtaek-si, Gyeonggi-do 17706, Republic of Korea Email: inae116@mitech.co.kr Phone: 82-70-4304-7450 Fax: 82-2-3463-4703	
Subject Devices	Trade Name: Device: Regulation Description: Review Panel: Regulation Number: Device Class: Product Code: Regulation Medical Specialty: Trade Name: Device: Regulation Description: Review Panel: Regulation Number: Device Class: Product Code: Regulation Medical Specialty:	HANAROSTENT® Esophagus TTS (CCC) Prosthesis, Esophageal Esophageal prosthesis Gastroenterology/Urology 21 CFR 878.3610 Class II ESW General & Plastic Surgery HANAROSTENT® Esophagus TTS (NCN) Prosthesis, Esophageal Esophageal prosthesis Gastroenterology/Urology 21 CFR 878.3610 Class II ESW General & Plastic Surgery

M.I.Tech
www.mitech.co.kr

HEAD OFFICE
174, HABUK2-GIL, JINWI-MYEON, PYEONGTAEK-SI, GYEONGGI-DO,
17706, REPUBLIC OF KOREA
TEL +82 31 662 5645 FAX +82 31 662 5648

Intended Use / Indications for Use	The HANAROSTENT® Esophagus TTS (CCC) and HANAROSTENT® Esophagus TTS (NCN) are intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors, and occlusion of concurrent esophageal fistulas.
Device Description	This self-expanding tubular prosthesis is designed to maintain esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors, and occlusion of concurrent esophageal fistulas. It consists of a self-expandable metal stent and a through-the scope delivery system. The self-expandable metal stent is made of nickel titanium alloy (Nitinol) wire, radiopaque markers made of gold wire, fully or partially covered silicone membrane, and repositioning lasso made of polyester. The delivery device is made of polymeric materials. 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 delivery system is compatible with a minimum 3.7mm working channel of a therapeutic endoscope. The HANAROSTENT® Esophagus TTS (CCC) and HANAROSTENT® Esophagus TTS (NCN) are intended for single use only.
Predicate Device	Device Classification Name: Prosthesis, Esophageal 510(k) Number: K123205 Device Name: Esophageal TTS Stent (currently commercialized as the Niti-S™ TTS Esophageal Stent) Applicant: Taewoong Medical Co., Ltd. Regulation Number: 21 CFR 878.3610 Classification Product Code: ESW Decision Date: 10/09/2013 Regulation Medical Specialty: General & Plastic Surgery 510(k) Review Panel: Gastroenterology/Urology Device Class: Class II
Mechanism of Action	The stent is loaded by the delivery device. Upon deployment of the stent, it imparts an outward radial force on the luminal surface of the esophagus to establish patency. The stent is constrained and loaded between the two sheaths. The delivery device and stent are introduced to the intended target location through the use of a 0.035 inch guidewire. Radiopaque markers allow visualizing and measuring placement accuracy. The delivery device is removed and discarded after deployment of the stent.

M.I.Tech
www.mitech.co.kr

HEAD OFFICE
174, HABUK2-GIL, JINWI-MYEON, PYEONGTAEK-SI, GYEONGGI-DO,
17706, REPUBLIC OF KOREA
TEL +82 31 662 5645 FAX +82 31 662 5648

Technological Characteristics	The subject devices and predicate device have substantially equivalent technological characteristics with only minor differences regarding: • Packaging: The subject devices do not have a Tyvek pouch. The predicate device has a Tyvek pouch. • Radiopaque marker material and quantity: The subject devices have 12 gold radiopaque markers. The predicate device has 10 platinum-iridium radiopaque markers. • Stent lengths: The subject device is offered in 60, 70, 80, 90, 100, 110, 120, 130, 140, and 150mm stent lengths. The predicate device is offered in 60, 80, 100, 120, 140, and 150mm stent lengths. • Lasso materials: The subject devices use a polyester lasso material. The predicate device uses a nylon lasso material. • Delivery device usable lengths: The subject devices offer an 1800mm or 2300mm delivery device. The predicate device offers an 1800mm delivery device. • Performance – Bench: o The subject and predicate devices have equivalent expansion forces. o The subject and predicate devices have equivalent compression forces. o The subject device's 1800mm delivery device and the predicate device's 1800mm delivery device have equivalent deployment forces. o The subject device's 2300mm delivery device has greater deployment force than the predicate device's 1800mm delivery device.

M.I.Tech
www.mitech.co.kr

HEAD OFFICE
174, HABUK2-GIL, JINWI-MYEON, PYEONGTAEK-SI, GYEONGGI-DO,
17706, REPUBLIC OF KOREA
TEL +82 31 662 5645 FAX +82 31 662 5648

FDA Guidance Documents	The following FDA guidance documents were consulted in preparing this premarket submission: • *Shelf Life of Medical Devices*, issued April 1991 • *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile*, issued January 2016 • *Guidance for Industry: Pyrogen and Endotoxins Testing: Questions and Answers*, issued June 2012 • *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*, issued June 16, 2016 • *Guidance for The Content of Premarket Notifications for Esophageal and Tracheal Prostheses*, issued April 28, 1998 • *Technical Considerations for Non-Clinical Assessment of Medical Devices containing Nitinol*, draft issued April 2019 • *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment*, issued December 2014 • *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*, issued August 2019
Performance - Bench	Bench testing was performed to confirm the safety and effectiveness of the proposed subject devices as compared to the predicate devices. Performance testing was performed as per the design control system. The following tests were conducted: • Deployment force • Deployment accuracy • Deployment in a simulated environment • Expansion force • Compression force • Dimensions • Corrosion • Tensile strength • Foreshortening • Trackability • Repositioning force • MR safety and compatibility
Performance - Animal	No animal performance data is submitted in this 510(k).
Performance - Clinical	No clinical performance data is submitted in this 510(k).

M.I.Tech
www.mitech.co.kr

HEAD OFFICE
174, HABUK2-GIL, JINWI-MYEON, PYEONGTAEK-SI, GYEONGGI-DO,
17706, REPUBLIC OF KOREA
TEL +82 31 662 5645 FAX +82 31 662 5648

Substantial Equivalence	The subject devices are substantially equivalent to the predicate device when evaluating intended use and technological characteristics. • The subject devices have the identical intended use as the predicate device. There are no differences between the subject device and predicate device with respect to intended use. The subject devices have different indications for use than the predicate device. The subject devices are additionally indicated for occlusion of concurrent esophageal fistulas. • The subject devices and predicate device are substantially equivalent with only minor technological differences. • These differences do not raise new questions of safety and effectiveness.
Conclusion	This comparison demonstrates the subject devices are substantially equivalent to the predicate device. The subject devices are as safe and effective as the predicate device and will perform as intended. Therefore, M.I. Tech respectfully requests market clearance for the subject devices.