July 23, 2021

M.I. Tech Co., Ltd
% Heidi Busz
Regulatory Consultant
Namsa
400 Highway 169 South, Suite 500
Minneapolis, MN 55426

Re: K201160
Trade/Device Name: HANAROSTENT Esophagus (CCC),
HANAROSTENT Esophagus (NCN)
Regulation Number: 21 CFR 878.3610
Regulation Name: Esophageal Prosthesis
Regulatory Class: Class II
Product Code: ESW
Dated: June 16, 2021
Received: June 21, 2021

Dear Heidi Busz:

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)*
K201160

Device Name
HANAROSTENT® Esophagus (CCC), HANAROSTENT® Esophagus (NCN)

Indications for Use *(Describe)*
The HANAROSTENT® Esophagus (CCC) and HANAROSTENT® Esophagus (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.

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5 510(k) Summary

Preparation Date:	April 30, 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: 82-2-3473-4702
Subject Devices:	Trade Name: HANAROSTENT® Esophagus (CCC) Device: Prosthesis, Esophageal Regulation Description: Esophageal prosthesis Review Panel: Gastroenterology/Urology Regulation Number: 21 CFR 878.3610 Device Class: Class II Product Code: ESW Trade Name: HANAROSTENT® Esophagus (NCN) Device: Prosthesis, Esophageal Regulation Description: Esophageal prosthesis Review Panel: Gastroenterology/Urology Regulation Number: 21 CFR 878.3610 Device Class: Class II Product Code: ESW
Intended Use / Indications for Use:	The HANAROSTENT® Esophagus (CCC) and HANAROSTENT® Esophagus (NCN) are intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors, and occlusion of concurrent esophageal fistula.

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Device Description:	This self-expanding tubular prosthesis is designed to maintain 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 an over the wire (OTW) delivery device. 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 one repositioning lasso at each end of the stent made of polymeric materials. 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 HANAROSTENT® Esophagus (CCC) and the HANAROSTENT® Esophagus (NCN) are intended for single use only.
Predicate Device:	Trade Name: Esophageal Stent System Applicant: Micro-Tech (Nanjing) Co., Ltd. 510(k) Number: K172813 Clearance Date: June 21, 2018 Device: Prosthesis, Esophageal Regulation Description: Esophageal prosthesis Review Panel: Gastroenterology/Urology Regulation Number: 21 CFR 878.3610 Device Class: Class II Product Code: ESW
Reference Devices:	Merit Medical Systems, Inc.'s EndoMAXX™ Fully Covered Esophageal Stent (K111611) Boston Scientific's WallFlex™ Esophageal Stents (K091510)
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 or 0.038 inch guidewire. Radiopaque markers allow visualizing and measuring placement accuracy. The delivery device is removed and discarded after deployment of the stent.

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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. • Shelf life: The subject device's shelf life is longer than the predicate device's shelf life. • Radiopaque marker material and quantity: The subject devices have a greater number of radiopaque markers and a different material than the predicate device. • Stent dumbbell diameters: The subject device has a larger dumbbell diameter range than the predicate device. • Stent lengths: The subject devices are offered in a greater number of stent lengths than the predicate device. • Lasso materials and quantity: The subject devices have two lassos of different materials than the predicate device. • Delivery device diameter: The subject devices offers delivery devices in two diameters. The predicate device offers one delivery device in one diameter. • Delivery device lengths: The subject delivery devices are longer than the predicate delivery device. • Performance test: - The subject and predicate devices have equivalent expansion forces. - The subject and predicate devices have equivalent compression forces. - The subject delivery device in both 6mm (18Fr) and 8mm (24Fr) diameters have lower deployment forces than the predicate delivery device when deploying the HANAROSTENT® Esophagus (CCC). - The subject delivery device in 6mm (18Fr) diameter has lower deployment force than the predicate delivery device when deploying the HANAROSTENT® Esophagus (NCN). The subject delivery device in 8mm (24Fr) diameter has equivalent deployment force to the predicate delivery device when deploying the HANAROSTENT® Esophagus (NCN).

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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 • *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 • *Guidance for FDA, Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices,* issued on March 22, 2016.
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: • Foreshortening • Expansion force • Compression force • Guidewire passage • Deployment force • Deploying accuracy • Tensile strength • Dimensions • Corrosion • 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).

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Substantial Equivalence:	The subject devices are substantially equivalent to the predicate devices when evaluating intended use and technological characteristics. • The subject devices have the exact same intended use/indications for use as the predicate device. • 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.