January 10, 2019

M.I. Tech Co., Ltd.
℅ Beryl St. Jeanne
Associate Regulatory Specialist
NAMSA
400 Highway 169 South, Suite 500
Minneapolis, MN 55426

Re: K183616
Trade/Device Name: HANAROSTENT LowAxTM Colon/Rectum (NNN)
HANAROSTENT LowAxTM Duodenum/Pylorus (NNN)
Regulation Number: 21 CFR§ 878.3610
Regulation Name: Esophageal Prosthesis
Regulatory Class: II
Product Code: MQR, MUM
Dated: December 21, 2018
Received: December 26, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel G. Walter Jr -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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)*

K183616

Device Name
HANAROSTENT LowAxTM Colon/Rectum (NNN)
HANAROSTENT LowAxTM Duodenum/Pylorus (NNN)

Indications for Use *(Describe)*

The HANAROSTENT LowAxTM Colon/Rectum (NNN) 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 structures.

The HANAROSTENT LowAxTM Duodenum/Pylorus (NNN) is indicated for the palliative treatment of pyloric or duodenal obstructions caused by malignant neoplasms.

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

510(k) Number	K183616	
Preparation Date:	December 21, 2018	
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 Device:	Trade Name: Common Name: Classification Regulation: Classification Name: Regulatory Class: Product Code: Classification Panel: Trade Name: Common Name: Classification Regulation: Classification Name: Regulatory Class: Product Code: Classification Panel:	HANAROSTENT® LowAx™ Colon/Rectum (NNN) Colon/Rectum Stent 21 CFR 878.3610 Esophageal Prosthesis Class II MQR Gastroenterology/Urology HANAROSTENT® LowAx™ Duodenum/Pylorus (NNN) Duodenum/Pylorus Stent 21 CFR 878.3610 Esophageal Prosthesis Class II MUM Gastroenterology/Urology

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Intended Use / Indications for Use:	The HANAROSTENT® LowAx™ Colon/Rectum (NNN) 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 structures. The HANAROSTENT® LowAx™ Duodenum/Pylorus (NNN) is indicated for the palliative treatment of pyloric or duodenal obstructions caused by malignant neoplasms.
Device Description:	This self-expanding tubular prosthesis designed to maintain patency of colorectal or duodenal obstructions caused by malignant tumors. It consists of a self-expandable metal stent and a delivery system. The self-expandable metal stent is made of nickel titanium alloy (Nitinol) wire and the delivery system is made of polymeric materials. The stent is loaded into the distal part of the delivery system. The HANAROSTENT® LowAx™ Colon/Rectum (NNN) and HANAROSTENT® LowAx™ Duodenum/Pylorus (NNN) are intended for single use only.
Predicate Device:	HANAROSTENT® LowAx™ Colon/Rectum (NNN); HANAROSTENT® LowAx™ Duodenum/Pylorus (NNN) 510(k) Number: K180180 Decision Date: 11/02/2018
Mechanism of Action:	The delivery system is supplied for either endoscopic or fluoroscopic delivery. The delivery system for use with endoscopes is mostly used at the department of internal treatment. The stent and delivery system are inserted through the channel of endoscopes and the stent is expanded and deployed at the target region. The fluoroscopic delivery device is used for inserting the device at the target position during fluoroscopic procedures. The stent is loaded by the delivery system and upon deployment of the stent it imparts an outward radial force on the luminal surface of the colon to establish patency. The stent is constrained and loaded between the two sheaths. Through the use of a 0.035 inch guidewire, the delivery system and stent are introduced to the intended target location. Radiopaque markers allow visualizing and measuring placement accuracy. After deployment of the stent the delivery system is removed and discarded.

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Technological Characteristics:	The subject device in this Traditional 510(k) submission is the exact same, identical device as predicate device K180180. M.I. Tech intends to leverage the identical technological characteristics provided with K180180. There have been no changes to the fundamental technological characteristics since K180180 received clearance. Therefore, the subject and predicate device have identical technological characteristics: - Biocompatible materials - Stent design - Delivery device design - Radiopaque markers - Single use - Method of placement - Method of deployment - Sterilization method - Packaging configuration and materials - Shelf life The only difference in technological characteristics between the subject and predicate device is that M.I. Tech is providing MR compatibility testing with this submission to support MR conditional labeling for the subject device.
Performance Testing:	The subject device in this Traditional 510(k) submission is the exact same, identical device as predicate device K180180. M.I. Tech intends to leverage the performance testing provided with K180180: - Axial force - Compression force - Corrosion - Deployment force - Deployment accuracy - Dimensions - Expansion force - Repositioning force - Stent separation - Tensile strength - Trackability M.I. Tech is providing new bench testing with this Traditional 510(k) in support of its subject device: - MR compatibility

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Substantial Equivalence:	The subject device in this Traditional 510(k) submission is the exact same, identical device as predicate device K180180. There are no differences between the subject device and the predicate device with respect to indications and intended use. The only difference in technological characteristics between the subject and predicate device is that M.I. Tech is providing MR Compatibility testing with this submission to support MR Conditional labeling for the subject device. Therefore, the subject device and the predicate device are identical devices, and support M.I. Tech's claim of substantial equivalence.
Conclusion:	The subject and predicate devices have the identical intended use/indications for use, device description, mechanism of action, technological characteristics, and performance testing. The only difference in technological characteristics between the subject and predicate device is that M.I. Tech is providing MR Compatibility testing with this submission to support MR Conditional labeling for the subject device. Performance data supports the safety of the subject device and demonstrates that the HANAROSTENT® LowAx™ Colon/Rectum (NNN) and the HANAROSTENT® LowAx™ Duodenum/Pylorus (NNN) are safe and effective and will perform as intended in the specified use conditions.