March 15, 2019

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

Re: K190141
Trade/Device Name: HANAROSTENT® LowAxTM Colon/Rectum (NNN)
Regulation Number: 21 CFR§ 878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: MQR
Dated: January 28, 2019
Received: January 29, 2019

Dear Beryl St. Jeanne:

This letter corrects our substantially equivalent letter of March 7, 2019.

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)*

K190141

Device Name
HANAROSTENT® LowAxTM Colon/Rectum (NNN)

Indications for Use *(Describe)*
The HANAROSTENT® LowAxTM Colon/Rectum (NNN) is indicated for the palliative treatment of colorectal strictures caused 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.

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

5 510(k) Summary

510(k) Number:	TBD
Preparation Date:	January 28, 2019
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: HANAROSTENT® LowAx™ Colon/Rectum (NNN) Common Name: Colon/Rectum Stent Classification Name: Esophageal Prosthesis Classification Regulation: 21 CFR 878.3610 Regulatory Class: Class II Product Code: MQR Classification Panel: Gastroenterology/Urology
Intended Use / Indications for Use:	The HANAROSTENT® LowAx™ Colon/Rectum (NNN) is indicated for the palliative treatment of colorectal strictures caused by malignant neoplasms and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.
Device Description:	This self-expanding tubular prosthesis designed to maintain patency of colorectal 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) is intended for single use only.
Predicate Device:	M.I. Tech Co., Ltd. HANAROSTENT® LowAx™ Colon/Rectum (NNN); HANAROSTENT® LowAx™ Duodenum/Pylorus (NNN) 510(k) Number: K183616 Decision Date: 01/10/2019

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

Reference Devices:	Cook Ireland Ltd. Evolution Duodenal Stent System - Uncovered; Evolution Colonic Stent System - Uncovered 510(k) Number: K163468 Decision Date: 05/04/2017 Boston Scientific Corp. Wallflex™ Enteral Colonic Stent with Anchor Lock Delivery System 510(k) Number: K061877 Decision Date: 09/15/2006 M.I. Tech Co., Ltd. HANAROSTENT® Biliary (NNN) 510(k) Number: K111149 Decision Date: 12/30/2011
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.
Technological Characteristics:	The subject device in this Special 510(k) submission is the exact same, identical device as predicate device K183616. M.I. Tech intends to leverage the identical technological characteristics provided with K183616. There have been no changes to the fundamental technological characteristics since K183616 received clearance. Therefore, the subject and predicate devices have identical technological characteristics: - Biocompatible materials - Stent design (except stent diameter size range) - Delivery device design - Radiopaque markers - Single use - Method of placement

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

	- Method of deployment - Sterilization method and processes - Packaging configuration and materials - Shelf life The only difference between the subject and predicate devices is that M.I. Tech is proposing an expanded stent diameter range to include a 25mm diameter stent with the subject device.
Performance Testing:	The subject device in this Special 510(k) submission is the exact same, identical device as predicate device K183616 with the exception of the 25mm stent diameter proposed with the subject device. M.I. Tech intends to leverage the testing provided with K183616: - Corrosion - MR compatibility M.I. Tech performed new bench testing to support the subject device: - Axial force - Compression force - Deployment force - Deployment accuracy - Dimensions - Expansion force - Repositioning force - Stent separation - Tensile strength - Trackability M.I. Tech performed new packaging validation testing to support the subject device: - Dye penetration - Seal strength - Sterility The new testing reports are not provided in this submission. The proposed 25mm diameter stent is supported with design control activities.
Substantial Equivalence:	The subject device in this Special 510(k) submission is the exact same, identical device as predicate device K183616. There are no differences between the subject device and the predicate device with respect to indications and intended use. The only difference between the subject and predicate devices is that the subject device proposes a 25mm diameter stent. Therefore, the subject device and the predicate device are identical devices, with the exception of stent diameter size range,

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

	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, and technological characteristics. The only difference between the subject and predicate devices is that M.I. Tech is proposing an expanded stent diameter range to include a 25mm diameter stent. Bench testing is being provided with this submission. Performance data supports the safety of the subject device and demonstrates that the HANAROSTENT® LowAx™ Colon/Rectum (NNN) is safe and effective and will perform as intended in the specified use conditions.