November 2, 2018

M.I. Tech Co., Ltd.
℅ Carol Buchert
Principal Medical Research Scientist
NAMSA
400 Highway 169 South, Suite 500
Minneapolis, MN 55426

Re: K180180
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: September 20, 2018
Received: September 24, 2018

Dear Carol Buchert:

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,

Jeffrey W. Cooper -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)*
K180180

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.

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.

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Pre-Market Notification 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

1. Submitter:

Name:	M.I.Tech Co., Ltd. 174 Habuk 2-gil, Jinwi-myeon, Pyeongtaek-si, Gyeonggi-do 17706, Republic of Korea
Contact:	Ms. Inae Kim / Manager Phone: + 82 70-4304-7450 Fax: +82 2-3473-4702

2. Device Name and Classification:

Proprietary Name:	HANAROSTENT® LowAx™ Colon/Rectum (NNN)
Common Name:	Colon/Rectum Stent
Classification Name:	Stent, Colonic, Metallic, Expandable
Classification:	21 CFR 878.3610
Product Code:	MQR
Third Party Reviewed:	No

Proprietary Name:	HANAROSTENT® LowAx™ Duodenum/Pylorus (NNN)
Common Name:	Duodenum/Pylorus Stent
Classification Name:	Stent, Duodenal, Metallic, Expandable
Classification:	21 CFR 878.3610
Product Code:	MUM
Third Party Reviewed:	No

3. Predicate Device:

Wallflex™ Enteral Colonic Stent with Anchor Lock Delivery System, K061877
Wallflex™ Enteral Duodenal Stent with Anchor Lock Delivery System, K062750

4. Description:

The same device description applies to both the HANAROSTENT® LowAx™ Colon/Rectum (NNN) and the HANAROSTENT® LowAx™ Duodenum/Pylorus (NNN).

This self-expanding tubular prosthesis is 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, and expanded in the body by pulling the outer sheath of the delivery system. The HANAROSTENT® LowAx™ Colon/Rectum (NNN) and HANAROSTENT® LowAx™ Duodenum/Pylorus (NNN) are intended for single use only.

5. 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 structures.

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

6. Technological Characteristics:

The proposed devices are substantially equivalent to the predicate devices, the Wallflex™ Enteral Colonic Stent with Anchor Lock Delivery System, K061877 and Wallflex™ Enteral Duodenal Stent with Anchor Lock Delivery System, K062750.

Both predicate devices share identical technological characteristics to each other. This is evidenced in 510(k)s K061877 and K02750. Both predicate devices cite the same predicate device within their submission: Boston Scientific Corporation's WallflexTM Enteral Colonic Stent with Anchor Lock Delivery System, K042065

Per K061877's *Technological Characteristics* section:
"The proposed Wallflex Enteral Colonic Stent with Anchor Lock Delivery System has the identical technological characteristics as the currently marketed Wallflex Enteral Colonic Stent with Anchor Lock Delivery System (K042065)."

Per K062750's *Technological Characteristics* section:
"The proposed WallFlex Enteral Duodenal Stent with Anchor Lock Delivery System has the identical technological (materials, construction, processing) characteristics as the predicate WallFlex Enteral Colonic Stent with Anchor Lock Delivery System and has the identical indication statement as the predicate Wallstent Enteral Endoprosthesis."

The proposed devices have the same characteristics as the predicate devices as listed below:

- Stent design
- Single use
- Sterilization method
- Method of placement
- Method of deployment
- Stent materials

The following technological differences exist between the proposed devices and the currently marketed predicate devices, the Wallflex™ Enteral Colonic Stent with Anchor Lock Delivery System and the Wallflex™ Enteral Duodenal Stent with Anchor Lock Delivery System.

- Stent diameter
- Stent length
- Delivery diameter
- Radiopaque markers

Please see the table below summarizing the technological characteristics of the subject devices and predicate devices.

	Subject Device #1	Subject Device #2	Predicate Device #1	Predicate Device #2	Comment
Device Name	HANAROSTENT® LowAx™ Colon/Rectum (NNN)	HANAROSTENT® LowAxTM Duodenum/Pylorus (NNN)	Wallflex™ Enteral Colonic Stent	Wallflex™ Enteral Duodenal Stent	N/A
Applicant	M.I. Tech Co., Ltd.	M.I. Tech Co., Ltd.	Boston Scientific Corp.	Boston Scientific Corp.	N/A
510(k) Number	TBD	TBD	K061877	K062750	N/A
Decision Date	TBD	TBD	09/15/2006	12/04/2006	N/A
Common Name	Colon/Rectum Stent	Duodenum/Pylorus Stent	Colon/Rectum Stent	Duodenum/Pylorus Stent	Identical
Indications for Use	The palliative treatment of colorectal strictures caused by malignant neoplasms and to relieve large bowel obstruction prior to colectomy in patients with malignant structures.	The palliative treatment of gastroduodenal obstructions caused by malignant neoplasms.	The palliative treatment of colonic strictures caused by malignant neoplasms and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.	The palliative treatment of gastroduodenal obstructions caused by malignant neoplasms.	Identical
Stent Diameter	20mm body with 25mm dumbbell 22mm body with 27mm dumbbell	20mm body with 25mm dumbbell 22mm body with 27mm dumbbell	22mm body with 27mm flare 25mm body with a 30mm flare	22mm body with 27mm flare	Equivalent. Subject device offers a model that is 2mm smaller in stent diameter for the body and dumbbell.
Stent Length	60mm 70mm 80mm 90mm 100mm 110mm 120mm	60mm 70mm 80mm 90mm 100mm 110mm 120mm	60mm 90mm 120mm	60mm 90mm 120mm	Equivalent. The length of subject device is subdivided within the smallest and largest lengths of predicate devices.
Delivery Diameter	3.40mm (10.2Fr)	3.40mm (10.2Fr)	3.33mm (10Fr)	3.33mm (10Fr)	Equivalent. The diameter of our delivery system is 0.06mm larger than the predicate device. This level is within a 5% tolerance of the dimension.

Single Use	Yes	Yes	Yes	Yes	Identical
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Identical
Method of Placement	Fluoroscopic, Endoscopic	Fluoroscopic, Endoscopic	Fluoroscopic, Endoscopic	Fluoroscopic, Endoscopic	Identical
Method of Deployment	Release by pulling outer sheath	Release by pulling outer sheath	Release by pulling outer sheath	Release by pulling outer sheath	Identical
Stent Materials	Nitinol	Nitinol	Nitinol	Nitinol	Identical
Radiopaque Marker Materials	Gold	Gold	N/A	N/A	Equivalent. Subject device has 12 gold radiopaque markers. The predicate device does not have radiopaque markers.
Shelf life	3 years	3 years	3 years	3 years	Identical

7. Performance Summary:

Appropriate bench testing was performed to confirm the safety and effectiveness of the proposed devices as compared to the identified predicate device.

The device specific FDA guidance document was consulted in preparing this premarket submission, Guidance for the content of premarket notifications for esophageal and tracheal prostheses issued April 28th, 1998. Performance testing was performed as per the design control system and the following tests were conducted:

- Axial force
- Compression force
- Corrosion
- Deployment force
- Deployment accuracy
- Dimensions
- Expansion force
- Repositioning force
- Stent separation
- Tensile strength
- Trackability

Biocompatibility safety was assessed in accordance with ISO 10993-1:2003, 2012.

8. Conclusions:

The non-clinical data supports the safety of the proposed devices 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.

The non-clinical data also demonstrates that the proposed device is substantially equivalent to the predicate devices, Wallflex™ Enteral Colonic Stent with Anchor Lock Delivery System (K061877) and Wallflex™ Enteral Duodenal Stent with Anchor Lock Delivery System (K062750).