November 18, 2021

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

Re: K213251
Trade/Device Name: HANAROSTENT Esophagus Asymmetric (CCC)
Regulation Number: 21 CFR 878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: Class II
Product Code: ESW
Dated: October 15, 2021
Received: October 19, 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,

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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K213251

Device Name
HANAROSTENT® Esophagus Asymmetric (CCC)

Indications for Use *(Describe)*

The HANAROSTENT® Esophagus Asymmetric (CCC) is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors, and occlusion of concurrent esophageal fistula.

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

| | | |
|---|---|---|
| Preparation Date: | September 29, 2021 | |
| Submitter: | M.I.Tech Co., Ltd.<br>174 Habuk 2-gil, Jinwi-myeon,<br>Pyeongtaek-si, Gyeonggi-do<br>17706, Republic of Korea<br>Phone: 82-31-662-5645<br>Fax: 82-31-662-5648 | |
| Primary Contact: | Sunyoung Jo<br>Regulatory Affairs 1 Team Manager<br>M.I.Tech Co., Ltd.<br>174 Habuk 2-gil, Jinwi-myeon,<br>Pyeongtaek-si, Gyeonggi-do<br>17706, Republic of Korea<br>Email: inae116@mitech.co.kr<br>Phone: 82-70-4304-7429<br>Fax: 82-70-8282-5642 | |
| Subject Devices: | Trade Name:<br><br>Device:<br>Regulation Description:<br>Review Panel:<br>Regulation Number:<br>Device Class:<br>Product Code:<br>Regulation Medical Specialty: | HANAROSTENT® Esophagus Asymmetric (CCC)<br><br>Prosthesis, Esophageal<br>Esophageal prosthesis<br>Gastroenterology/Urology<br>21 CFR 878.3610<br>Class II<br>ESW<br>General & Plastic Surgery |
| Intended Use / Indications for Use: | The HANAROSTENT® Esophagus Asymmetric (CCC) is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors, and occlusion of concurrent esophageal fistula. | |

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

| | | |
|---|---|---|
| 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 a delivery device. The self-expandable metal stent is made of nickel titanium alloy (Nitinol) wire with fully covered silicone membrane, and 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 Asymmetric (CCC) is intended for single use only. | |
| Predicate Device: | Trade Name: | HANAROSTENT® Esophagus (CCC) |
| | Applicant: | M.I.Tech Co., Ltd. |
| | 510(k) Number: | K201160 |
| | Clearance Date: | July 23, 2021 |
| | Device: | Prosthesis, Esophageal |
| | Regulation Description: | Esophageal prosthesis |
| | Review Panel: | Gastroenterology/Urology |
| | Regulation Number: | 21 CFR 878.3610 |
| | Device Class: | Class II |
| | Product Code: | ESW |
| | Regulation Medical Specialty: | General & Plastic Surgery |
| Reference Devices: | Boston Scientific's WallFlex™ Esophageal Stents (K091510)<br>Boston Scientific's Ultraflex ™ Esophageal Stents (K955347) | |
| Comparison to the Predicate: | Both the subject and predicate devices are designed to maintain patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors, and occlusion of concurrent esophageal fistulas.<br>The subject device and the predicate device have the same material, manufacturing process, sterilization method, and operation method, but have different stent diameters, dumbbell diameters and lengths. | |

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 intended use of the subject device, HANAROSTENT® Esophagus Asymmetric (CCC), is identical to the predicate device, HANAROSTENT® Esophagus (CCC).<br>The subject device is identical to the delivery device of predicate device in working length, outer diameter, method of placement, and guidewire compatibility.<br>The subject device has same stent materials as the predicate device and is similar in terms of performance. The subject device is similar to the reference device, Boston Scientific's WallFlex™ Esophageal Stents (K091510) and Ultraflex ™ Esophageal Stents (K955347), in terms of stent diameter, dumbbell diameter and length. |
| FDA Guidance Documents: | The following FDA guidance documents were consulted in preparing this premarket submission:<br>• *Guidance for The Special 510(k) Program,* issued September 13, 2019<br>• *Shelf Life of Medical Devices,* issued April 1991<br>• *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile,* issued January 2016<br>• *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<br>• *Guidance for The Content of Premarket Notifications for Esophageal and Tracheal Prostheses,* issued April 28, 1998<br>• *Technical Considerations for Non-Clinical Assessment of Medical Devices containing Nitinol,* draft issued April 2019<br>• *Use of International Standard ISO 14971, " Medical devices — Application of risk management to medical devices",* issued December, 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

| | |
|---|---|
| Performance Testing: | 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:<br>• Foreshortening<br>• Expansion force<br>• Compression force<br>• Guidewire passage<br>• Deployment force<br>• Deploying accuracy<br>• Dimensions<br>No animal and clinical performance data is submitted in this 510(k). |
| Substantial Equivalence: | The subject devices are substantially equivalent to the predicate devices when evaluating intended use and technological characteristics.<br>• The subject device has exact same intended use/indications for use as the predicate.<br>• The subject devices and predicate device are substantially equivalent with only minor technological differences.<br>• 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. |