October 30, 2025

M.I. Tech Co., Ltd.
℅ Monica Montanez
Principal Strategy Consultant
NAMSA
381 Lark Lane
Bailey, Colorado 80421

Re: K253327
Trade/Device Name: HANAROSTENT Esophagus Upper (CCC)
Regulation Number: 21 CFR 878.3610
Regulation Name: Esophageal Prosthesis
Regulatory Class: Class II
Product Code: ESW
Dated: September 29, 2025
Received: September 30, 2025

Dear Monica Montanez:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253327

Please provide the device trade name(s).

HANAROSTENT Esophagus Upper (CCC)

Please provide your Indications for Use below.

The HANAROSTENT® Esophagus Upper (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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

M.I.Tech
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510(k) Summary

Preparation Date:	October 20, 2025	
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:	Jeongeun Park Regulatory Affairs Manager M.I.Tech Co., Ltd. 174 Habuk 2-gil, Jinwi-myeon, Pyeongtaek-si, Gyeonggi-do 17706, Republic of Korea Email: jepark@mitech.co.kr Phone: 82-10-4456-9150 Fax: 82-70-8282-5642	
Subject Devices:	Trade Name: Device: Regulation Description: Review Panel: Regulation Number: Device Class: Product Code: Regulation Medical Specialty:	HANAROSTENT® Esophagus Upper (CCC) Prosthesis, Esophageal Esophageal prosthesis Gastroenterology/Urology 21 CFR 878.3610 Class II ESW General & Plastic Surgery
Intended Use / Indications for Use:	The HANAROSTENT® Esophagus Upper (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.	

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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 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 Upper (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
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. The subject device and the predicate device have the same material, manufacturing process, sterilization method, and operation method, but have different stent diameters, type of stent proximal head, diameters and lengths of stent proximal head.
Technological Characteristics:	The intended use of the subject device, HANAROSTENT® Esophagus Upper (CCC), is identical to the predicate device, HANAROSTENT® Esophagus (CCC). The subject device is identical to the delivery device of predicate device in working length, outer diameter, method of placement, and guidewire compatibility. The subject device has same stent materials as the predicate device and is similar in terms of performance.
FDA Guidance Documents:	The following FDA guidance document were consulted in preparing this premarket submission: • *Guidance for The Content of Premarket Notifications for Esophageal and Trach eal Prostheses,* issued April 28, 1998

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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: • Foreshortening • Expansion force • Compression force • Guidewire passage • Deployment force • Deploying accuracy • Dimensions • Bonding strength • Lasso tensile strength 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. • The subject device has exact same intended use/indications for use as the predic ate. • The subject devices and predicate device are substantially equivalent with only m inor technological differences. • These differences do not raise new questions of safety and effectiveness.
Conclusion:	This comparison demonstrates the subject device 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.