May 11, 2021

M.I.Tech Co., Ltd.
% Kelly Kucharczyk
Manager, Regulatory and Medical Writing Services
NAMSA
400 Highway 169 South, Suite 500
Minneapolis, MN 55426

Re: K202973
Trade/Device Name: HANAROSTENT Benefit Biliary (NNN)
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: Class II
Product Code: FGE
Dated: April 8, 2021
Received: April 12, 2021

Dear Kelly Kucharczyk:

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 and the limitations described below. 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.

The OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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,

Courtney H. Lias, Ph.D.
Acting Office Director
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)*
K202973

Device Name
HANAROSTENT® Benefit™ Biliary (NNN)

Indications for Use *(Describe)*
The HANAROSTENT® Benefit™ Biliary (NNN) is indicated for the palliation of malignant strictures in the biliary tree.

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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510(k) Summary

510(k) Number	K202973	
Preparation Date	May 11, 2021	
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, PhD 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: 82-2-3463-4703	
Subject Device	Device Trade Name: Device Classification Name: Regulation Number: Regulation Description: Device Class: Classification Product Code: Regulation Medical Specialty: 510(k) Review Panel:	HANAROSTENT® Benefit™ Biliary (NNN) Stents, Drains And Dilators For The Biliary Ducts 21 CFR 876.5010 Biliary catheter and accessories Class II FGE Gastroenterology/Urology Gastroenterology/Urology
Device Description	The HANAROSTENT® Benefit™ Biliary (NNN) is a self-expanding tubular prosthesis designed to maintain patency of biliary obstructions caused by malignant tumors. 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. 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 stent and delivery device are provided sterile and are intended for single use only.	
Intended Use / Indications for Use	The HANAROSTENT® Benefit™ Biliary (NNN) is indicated for the palliation of malignant strictures in the biliary tree.	
Mechanism of Action	The stent is loaded by the delivery device. Upon deployment of the stent, it imparts an outward radial force on the luminal surface of the biliary tract to establish patency.	
Predicate Device	510(k) Number: Applicant: Trade Name: Device Classification Name: Regulation Number: Regulation Description: Device Class: Classification Product Code: Regulation Medical Specialty: 510(k) Review Panel:	K111149 M.I.Tech Co., Ltd. HANAROSTENT® Biliary (NNN) Stents, Drains And Dilators For The Biliary Ducts 21 CFR 876.5010 Biliary catheter and accessories Class II FGE Gastroenterology/Urology Gastroenterology/Urology

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Reference Devices	<u>Reference Device 1:</u> 510(k) Number: K163018 Applicant: Cook Ireland Ltd. Trade Name: Zilver 635 Biliary Stent Device Classification Name: Stents, Drains And Dilators For The Biliary Ducts Regulation Number: 21 CFR 876.5010 Regulation Description: Biliary catheter and accessories Device Class: Class II Classification Product Code: FGE Regulation Medical Specialty: Gastroenterology/Urology 510(k) Review Panel: Gastroenterology/Urology <u>Reference Device 2:</u> 510(k) Number: K140630 Applicant: Boston Scientific Trade Name: Wallflex Biliary RX Stent System Device Classification Name: Stents, Drains And Dilators For The Biliary Ducts Regulation Number: 21 CFR 876.5010 Regulation Description: Biliary catheter and accessories Device Class: Class II Classification Product Code: FGE Regulation Medical Specialty: Gastroenterology/Urology 510(k) Review Panel: Gastroenterology/Urology
Technological Characteristics	The subject device and predicate device have substantially equivalent technological characteristics with only minor differences regarding: • Stent shape: the subject device has straight ends; the predicate has flared ends. • Stent radiopaque marker quantity: the subject device has 9; the predicate device has 12. • Stent diameters: the subject device offers 6mm and 8mm diameter stents; the predicate device offers 8mm and 10mm diameter stents. • Stent lengths: the subject device offers a 110mm length stent; the predicate device does not offer a 110mm length stent. • Delivery device diameter: the subject delivery device diameter is 5.9Fr; the predicate delivery device diameter is 7.08Fr. • Stenting procedure: two subject devices can be implanted; only one predicate device is typically implanted. • Performance testing: The subject and predicate devices have equivalent deployment, expansion, and compression forces. • Corrosion testing: The subject and predicate devices have equivalent simulated single stent implant corrosion susceptibility. The subject and reference devices have equivalent simulated stent-in-stent implant corrosion susceptibility.

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FDA Guidance Documents	The following FDA guidance documents were consulted in preparing this premarket submission: • *Metal Expandable Biliary Stents - Premarket Notification (510(k)) Submissions*, issued July 2019 • *Shelf Life of Medical Devices*, issued April 1991 • *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile*, issued January 2016 • *Guidance for Industry: Pyrogen and Endotoxins Testing: Questions and Answers*, issued June 2012 • *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*, issued June 2016 • *Technical Considerations for Non-Clinical Assessment of Medical Devices containing Nitinol*, issued October 2020 • *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment*, issued December 2014 • *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*, issued August 2019
Performance - Bench	Bench testing was performed to confirm the safety and effectiveness of the subject device as compared to the predicate device. Testing was performed as per the design control system. The following tests were conducted: • Design Verification Testing o Foreshortening o Crossing Profile o Trackability o Deployment Force o Withdrawal (Repositioning) Force o Expansion Force o Stent Separation o Deployment Accuracy o Compression Force o Stent Integrity o Stent Dimensional Verification o Delivery System Tensile Strength • Biocompatibility Testing • MRI Safety and Compatibility Testing • Corrosion Testing: o Single stent o Overlapping stents
Performance - Animal	No animal performance data is submitted in this 510(k).
Performance - Clinical	No clinical performance data is submitted in this 510(k).
Substantial Equivalence	The subject device is substantially equivalent to the predicate device when evaluating intended use and technological characteristics.
Conclusion	This comparison demonstrates the subject device is substantially equivalent to the predicate device. The subject device is as safe and effective as the predicate device and will perform as intended.