December 31, 2020

M.I. Tech Co., Ltd.
% Beryl Jeanne
Regulatory Consultant
Namsa
400 Highway 169 South, Suite 500
Minneapolis, Minnesota 55426

Re: K201342
Trade/Device Name: HANAROSTENT® Trachea/Bronchium (CCC)
Regulation Number: 21 CFR 878.3720
Regulation Name: Tracheal Prosthesis
Regulatory Class: Class II
Product Code: JCT
Dated: May 19, 2020
Received: May 20, 2020

Dear Beryl Jeanne:

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,

Brandon L. Blakely, Ph.D.
Acting Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201342

Device Name
HANAROSTENT® Trachea/Bronchium (CCC)

Indications for Use *(Describe)*
The HANAROSTENT® Trachea/Bronchium (CCC) is indicated for use in the treatment of tracheobronchial strictures 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.

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510(k) Summary

Preparation Date	December 14, 2020	
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: 82-2-3463-4703	
Subject Device	Trade Name:	HANAROSTENT® Trachea/Bronchium (CCC)
	Common Name:	Prosthesis, Tracheal, Expandable
	Classification Product Code:	JCT
	Regulation Number:	21 CFR 878.3720
	Classification Name:	Tracheal Prosthesis
	Device Class:	Class II
	Regulation Medical Specialty:	General & Plastic Surgery
	510(k) Review Panel	Anesthesiology
Primary Predicate Device	EndoChoice, Inc.'s BONASTENT® Tracheal/Bronchial (K140472)	
Reference Predicate Device	Alveolus, Inc's AERO™ Tracheobronchial Stent Technology System (K082284)	
Device Description	The HANAROSTENT® Trachea/Bronchium (CCC) is a self-expanding tubular prosthesis designed to maintain patency of tracheal or/and bronchial 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 that is fully covered with a silicone membrane and has one repositioning lasso at one end of the stent. 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® Trachea/Bronchium (CCC) is indicated for use in the treatment of tracheobronchial strictures caused by malignant neoplasms.	
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 trachea/bronchium to establish patency. The stent is constrained and loaded between the two sheaths. The delivery device and stent are introduced to the intended target location through the use of a 0.035 inch guidewire. Radiopaque markers allow visualizing and measuring placement accuracy. The delivery device is removed and discarded after deployment of the stent.	

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Device Name	HANAROSTENT® Trachea/Bronchium (CCC)	BONASTENT® Tracheal/Bronchial Stent System	AERO™ Tracheobronchial Stent System
Applicant	M.I.Tech Co., Ltd.	EndoChoice, Inc.	Alveolus, Inc.
510(k) Number	TBD	K140472	K082284
Device Classification Name	Prosthesis, Tracheal, Expandable	Prosthesis, Tracheal, Expandable	Prosthesis, Tracheal, Expandable
Regulation Number	21 CFR 878.3720	21 CFR 878.3720	21 CFR 878.3720
Regulation Description	Tracheal Prosthesis	Tracheal Prosthesis	Tracheal Prosthesis
Device Class	Class II	Class II	Class II
Classification Product Code	JCT	JCT	JCT
Regulation Medical Specialty	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery
510(k) Review Panel	Anesthesiology	Anesthesiology	General & Plastic Surgery
Intended Use/ Indications for Use	The HANAROSTENT® Trachea/Bronchium (CCC) is indicated for use in the treatment of tracheobronchial strictures caused by malignant neoplasms.	The BONASTENT® Tracheal/Bronchial Stent System is indicated for the treatment of tracheobronchial strictures caused by malignant neoplasms.	The Alveolus AERO™ Tracheobronchial Stent System is indicated for use in the treatment of tracheobronchial strictures caused by malignant neoplasms.
Patient Population	Adults	Unknown	Unknown
Stent Body	Nitinol	Nitinol	Nitinol
Stent Radiopaque Markers	Gold	Platinum	None
Stent Membrane	Fully coated silicone membrane	Fully coated silicone membrane	Fully coated polyurethane membrane
Stent Lasso	One end of the stent	N/A	One end of the stent
Stent Diameter Range	10-20mm	10-20mm	10-20mm
Stent Length Range	20-80mm	20-80mm	20-80mm
Delivery Device Diameter	4mm (12Fr)	2.67, 3, 3.33, 4mm (8, 9, 10, 12Fr)	5.33, 7.33mm (16, 22Fr)
Delivery Device Usable Length Range	500-900mm	500-900mm	630-560mm
Method of Placement	Bronchoscopy	Bronchoscopy	Bronchoscopy

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Method of Deployment	Release by pulling outer sheath	Release by pulling outer sheath	Release by pulling outer sheath
Provided Sterile	Yes	Yes	No
Sterilization Method	EO	EO	N/A. Non-sterile.
Single-Use Only	Yes	Yes	Yes
Packaging	Blister (Forming case+ Tyvek film) Inner box Outer box	Forming case Tyvek Pouch Inner box Outer box	Forming case Tyvek Pouch Inner box Outer box
Shelf Life	3 years	3 years	Unknown
MR Compatibility	MR conditional	MR conditional	MR conditional

FDA Guidance Documents	The following FDA guidance document was consulted in preparing this premarket submission: • *Guidance for The Content of Premarket Notifications for Esophageal and Tracheal Prostheses*, dated April 28, 1998. • *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.
Biocompatibility	The following biocompatibility testing was completed to determine the subject device is biocompatible for its intended use: • Cytotoxicity (ISO 10993-5) • Sensitization (ISO 10993-10) • Intracutaneous Reactivity (ISO 10993-10) • Acute Systemic Toxicity (ISO 10993-11) • Pyrogenicity (ISO 10993-11, USP <151>) • Genotoxicity (ISO 10993-3, OECD Test No. 471, OECD Test No. 490) • Implantation (ISO 10993-6) • Chemical Characterization (ISO 10993-17, ISO 10993-18)
Performance - Bench	The following bench testing was completed to determine the subject device will perform as intended: • Deployment Force • Expansion Force • Compression Force • Dimensions • MR Safety and Compatibility • Axial Force • Trackability • Repositioning Force • Deploying Accuracy • Foreshortening • Corrosion • Fatigue • Repositioning Force • Repositioning Function • Tensile Strength (delivery device and lasso)

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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	Subject device HANAROSTENT® Trachea/Bronchium (CCC) is substantially equivalent to primary predicate device BONASTENT® Tracheal/Bronchial Stent System (K140472) when evaluating intended use and technological characteristics: • Subject device HANAROSTENT® Trachea/Bronchium (CCC) has the identical intended use as primary predicate device BONASTENT® Tracheal/Bronchial Stent System. There are no differences between the subject device and primary predicate device with respect to indications and intended use. • Subject device HANAROSTENT® Trachea/Bronchium (CCC) has minor technological differences compared to predicate device BONASTENT® Tracheal/Bronchial Stent System regarding packaging materials, stent repositioning lasso, radiopaque marker materials, delivery device diameter, and performance testing results. • These technological characteristic differences do not raise new questions of safety and effectiveness. Therefore, the subject and predicate devices are considered substantially equivalent.
Conclusion	M.I.Tech determined subject device HANAROSTENT® Trachea/Bronchium (CCC) is substantially equivalent to the primary predicate device BONASTENT® Tracheal/Bronchial Stent System when evaluating intended use and technological characteristics, is biocompatible for its intended use, and will perform as intended. Therefore, M.I.Tech respectfully requests marketing clearance for subject device HANAROSTENT® Trachea/Bronchium (CCC).