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K111149
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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. Sponsor Information:

Company Name & Address:	M.I.Tech Co., Ltd. 241-3 Habuk-ri, Jinwi-myeon, Pyeongtaek-si, Gyeonggi-do 451-864 Republic of Korea
Contact Person:	Danny Lee
Contact Title:	Manager
Contact Phone Number:	+82 31 662-5645
Contact Fax Number:	+82 31 662-5648
Date of Summary:	October 21, 2011

2. Device Name and Classification:

Common and Usual Name:	Biliary Catheter
Proprietary Name:	HANAROSTENT® Biliary (NNN)
Classification Name:	Biliary Catheter
Classification Regulation:	21 CFR 876.5010
Regulatory Class:	Class 2
Product Code:	FGE
Performance Standards:	No applicable performance standards have been issued under section 514 or under section 513(b) of the Food, Drug and Cosmetic Act.

3. Predicate Device(s): Niti-S Biliary Stent & Introducer, K073667

4. Description of Device:

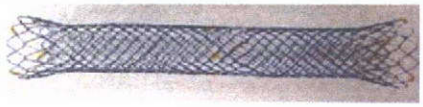
The HANAROSTENT® Biliary (NNN) is a self-expanding uncoated tubular prosthesis designed to maintain patency of bile duct strictures caused by malignant tumors. It consists of a self-expanding metal stent and delivery system. The Biliary stent is made of Nickel Titanium alloy (Nitinol) wire, which expands at body temperature. The stent is deployed with supplied introducers for percutaneous and endoscopic use.

The Stent is available in two diameters (8 and 10mm) and eight lengths (40mm, 50mm, 60mm, 70mm, 80mm, 90mm, 100mm, and 120mm). User preference, individual patient condition and/or anatomy determine the appropriate type and size for use. The HANAROSTENT® Biliary (NNN) is intended for single use only.

5. Indications for Use:

The HANAROSTENT® Biliary (NNN) is indicated for the palliation of malignant structures in the biliary tree.

6. Comparison with Predicate Device(s):

Proprietary Name	HANAROSTENT® Biliary (NNN)	Niti-S Biliary Stent & Introducer
Indications for use	The HANAROSTENT® Biliary (NNN) is indicated for the palliation of malignant strictures in the biliary tree.	The Niti-S Biliary Stent is indicated for the palliation of malignant strictures in the biliary tree.
Design (Stent)	 Nitinol wire Cylinder shape, Diamond pattern, Flare shape Length; 40, 50, 60, 70, 80, 90, 100, 120mm Diameter; 8, 10mm Marker; 12 gold markers	 Nitinol wire Cylinder shape, Diamond pattern Non Flare shape Length; 40, 50, 60, 70, 80, 90, 100, 120 mm Diameter; 8, 10mm Markers; 8 Pt/Ir 2 STS 316L
Design (Introducer)	 Braided tube type Length; 60, 180cm Diameter; 2.36mm	 Co-axial tube type Usable Length; 50,60,180,190cm Diameter; 2.7, 2.8mm
Single Use	Yes	Yes
Sterile	EO Sterilization	EO Sterilization
Method of Placement	Percutaneous, Endoscopic	Percutaneous, Endoscopic
Method of Deployment	Release by pulling Outer sheath	Release by pulling Outer sheath
Materials	Stent - Nitinol Marker – Gold Introducer – Teflon, PEEK, ABS, SUS 304, PC	Stent - Nitinol Marker – Pt/Ir, STS316L Introducer – Teflon, PE, ABS

The HANAROSTENT® Biliary (NNN) has the same device characteristics, composition, function, and intended use as the predicate device, such as the Niti-S Biliary Stent & Introducer.

The minor differences between the devices are introducer type, marker materials, and dimensional differences. These minor differences do not raise new questions of safety or efficacy of the device.

Based on the comparison of intended use and technical features, the HANAROSTENT® Biliary (NNN) is substantially equivalent to the identified predicate device.

7. **Performance Summary:**

Appropriate bench testing including compression force, expansion force, deployment force and accuracy, withdrawal force and corrosion tests were performed to confirm the safety and effectiveness of the HANAROSTENT® Biliary (NNN) stent as compared to the identified predicate device. Biocompatibility safety was assessed in accordance with ISO10993-1:2003.

Based on the performance comparisons, the HANAROSTENT® Biliary (NNN) is substantially equivalent to the identified predicate device.

8. **Conclusions:**

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification M.I.Tech Co., Ltd. concludes that the HANAROSTENT® Biliary (NNN) stent and introducer system is safe and effective, performs at least as well, and is substantially equivalent to the predicate devices as described herein and similar devices legally commercially available.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

M.I.Tech Co., Ltd.
% Mr. Paul Sumner
Vice President
Arkin Consulting Group
1733 Canton Lane
MARIETTA GA 30062

DEC 30 2011

Re: K111149
Trade/Device Name: HANAROSTENT® Biliary (NNN)
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: December 19, 2011
Received: December 22, 2011

Dear Mr. Sumner:

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Christy Foreman
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111149

Device Name: HANAROSTENT® BILIARY (NNN)

Indications For Use: The HANAROSTENT® BILIARY (NNN) is indicated for the palliation of malignant strictures in the biliary tree.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Colleen M. Pollard

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111149