April 11,2018

Suzhou Innomed Medical Device Co., Ltd
c/o Ms. Darlene Garner
Regulatory Affairs Consultant
113 Garner Cove
Georgetown, Texas 78633

Re: K172187
Trade/Device Name: Inno-Hydrowire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: March 13, 2018
Received: March 14, 2018

Dear Ms. Garner:

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. 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); 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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K172187

Device Name
Inno-Hydrowire

Indications for Use *(Describe)*

The Inno-Hydrowire is intended to direct a catheter to the desired anatomical location in the vasculatory system during diagnostic or interventional procedures. This device is not intended for neurovascular or coronary use.

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

This 510(k) summary is provided per the requirements of 21 CFR Part 807.92.

Applicant: Suzhou Innomed Medical Device Co., LTD
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Applicant Contact: Darlene Garner
Regulatory Affairs Consultant
979/864-9232
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Date Prepared: April 5, 2018

Trade Name: Inno-Hydrowire

Common Name: Guidewire

Classification Name: Wire, Guide, Catheter

Regulation Name: Catheter guide wire

Regulation Number: 21CFR Part 870.1330

Product Code: DQX

Classification: Class II

Classification Panel: Division of Cardiovascular Devices

Predicate device: Terumo Radifocus® Guidewire (K863138)

Device Description

The Inno-Hydrowire is intended to direct a catheter to the desired anatomical location in the vasculatory system during diagnostic or interventional procedures. It is provided sterile and is intended for single use only. It consists of a Nickel-Titanium alloy core wire; a polymer

coating (Pebax containing BaSO4 for X-Ray visibility); and a hydrophilic coating applied to the entire wire. There are two shaft configurations: standard and stiff. There are two distal tip shapes: straight and angled. The Inno-Hydrowire includes a 3cm flexible tip. The Inno-Hydrowire is packaged in a plastic dispenser that is contained within an individual package. A Torquer is included which connects to the proximal end of the guidewire utilized for rotating and controlling the guidewire. The Hydrowires are packaged within a cardboard box which contains five individual guidewires.

Intended Use

The Inno-Hydrowire is intended to direct a catheter to the desired anatomical location in the vasculatory system during diagnostic or interventional procedures. This device is not intended for neurovascular or coronary use.

Principle of Operation

The Inno-Hydrowire is operated manually or by a manual process.

Substantial Equivalence

The Inno-Hydrowire was found to be substantially equivalent to the Terumo Radifocus® Guidewire, Premarket Notification K863138. A comparison of the technological characteristics is summarized in the table below:

Comparison of the Inno-Hydrowire and Predicate Device

Comparison Feature	Inno-Hydrowire Guidewire	Radifocus® Guidewire
Principle of Operation	Manual	Manual
Indications for use	Intended to direct a catheter to the desired anatomical location in the vasculatory system during diagnostic or interventional procedures. This device is not intended for neurovascular.	Intended to direct a catheter to the desired anatomical location during diagnostic or interventional procedures.
Core Wire	Nickel Titanium	Nickel Titanium
Jacket	Pebax	Polyurethane
Radiopaque Material	Barium Sulfate (BaSO4)	Tungsten

Comparison Feature	Inno-Hydrowire Guidewire	Radifocus® Guidewire
Hydrophilic Coating	Polyvinyl Pyrrolidon (PVP)	Half-ester methyl vinyl ether-maleic anhydride copolymer
Adhesive (Core/Jacket)	Extrusion	Extrusion
Distal Tip Configurations	Straight, Angle,	Straight, Angle, and J shape
Lengths	80cm, 150cm, 180cm and 260cm	120cm, 150cm, 180cm, 220cm, 260cm, 300cm, 400cm and 450cm
Diameters	0.014",0.018'",0.025",0.032" 0.035" and 0.038"	0.018",0.025",0.032", 0.035" and 0.038"
Sterility	Ethylene Oxide	Ethylene Oxide
Shelf Life	Two Years	Two Years

The Inno-Hydrowire does not have the exact intended use as the predicate Radifocus Guidewire in that the Inno-Hydrowire is specific to the vasculatory system.

The Inno-Hydrowire is substantially equivalent to the Radifocus Guidewire in technology / principal of operation, and is similar in the material and design. The main differences between the Inno-Hydrowire device and the predicate device are the sizes and the material. These differences do not affect the intended use or performance of the Inno-Hydrowire. Performance (bench) testing and biocompatibility testing were performed to demonstrate that the proposed device performs as intended.

Non-Clinical Performance Testing

Performance testing has been conducted in accordance with FDA guidance document *Coronary and Cerebrovascular Guidewire Guidance, January 1995, ISO 11070:2014, Sterile single-use intravascular catheter introducers.* The results of the following performance tests have demonstrated substantial equivalence to the predicate device.

- Tensile Strength
- Torque Strength
- Tip Flexibility
- Surface Lubricity
- Corrosion
- Kink Resistance
- Torqueability
- Particulate
- Coating Adherence/Integrity
- Dimensional Verification
- Radiodetectability

Biocompatibility Testing

Biocompatibility testing was performed to ensure the material safety in accordance with the tests recommended in the I*nternational Standard ISO 10993-1. "Biological Evaluation of Medical Devices Part-I: Evaluation and testing within a risk management process."* The Inno-Hydrowire is classified as an Externally Communicating Device, Circulating Blood, Limited Contact (≤24h).

The following biocompatibility testing, performed in accordance with ISO-10993, has been performed on the Inno-Hydrowire:

• Cytotoxicity	IS0 10993-5
• Sensitization (Kligman Maximization)	ISO 10993-10
• Intracutaneous Injection	ISO 10993-10
• Acute Systemic Toxicity	SO 10993-1l
• Rabbit Pyrogen	SO 10993-1l
• Hemolysis	ASTM F756-08 /ISO 10993-4
• In Vitro Hemocompatibility	ISO 10993-4
• Lee & White Clotting Time	ISO 10993-4
• Dog Thrombogenicity	ISO 10993-4
• Complement Activation Assay(C3a)	ISO 10993-4
• Complement Activation Assay(Sc5b-9)	ISO 10993-4

Test results for all biocompatibility testing met the applicable test requirements.

Sterilization

Sterilization conditions have been validated in accordance with *lSO 11135, Sterilization of health - care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices.* The device is sterilized to a Sterility Assurance Level (SAL) of 10^{-6}. Residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) will meet requirements for limited exposure devices (contact up to 24 hours) prior to use based on *ISO 10993-7, Biological Evaluation of medical devices- Part 7: Ethylene Oxide Sterilization residuals.*

Pyrogenicity

The Inno-Hydrowire has been evaluated for non-endotoxin related factors. The rabbit pyrogen test as described in ANSI/AAMI/ISO 10993-11. The results concluded that the Inno-Hydrowire does not elicit a material mediated pyrogenic response.

Conclusion

The Inno-Hydrowire was found to be substantially equivalent in its design, intended use, technology, principal of operation, and performance to the predicate device. There are no significant differences between the Inno-Hydrowire and the predicate device.

Suzhou Innomed has demonstrated that the proposed Inno-Hydrowire Guidewire is substantially equivalent to the predicate device (Terumo Radifocus Guidewire).