March 11, 2019

Suzhou Innomed Medical Device Co., Ltd

% Darlene Garner
Regulatory Consultant
Darlene Garner
113 Garner Cove
Georgetown, Texas 78633

Re: K182553
Trade/Device Name: Inno-Pathwire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: February 6, 2019
Received: February 7, 2019

Dear Darlene 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. 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/cfpmm/pmm.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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Lydia S. Glaw -S

Digitally signed by
Lydia S. Glaw -S
Date: 2019.03.11
16:04:52 -04'00'

for
Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

Device Name
Inno-Pathwire

Indications for Use (Describe)
The Inno-Pathwire is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA).

Type of Use (Select one or both, as applicable)

- [x] 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.

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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
510(k) SUMMARY

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

Applicant: Suzhou Innomed Medical Device Co., LTD
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Applicant Contact: Darlene Garner
Regulatory Affairs Consultant
979/864-9232
darlene.garner50@yahoo.com

Date prepared: March 7, 2019

Trade Name: Inno-Pathwire

Common Name: Guidewire

Classification Name: Device - 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: HI-TORQUE BALANCE MIDDLEWEIGHT Guide Wire with Hydrocoat Hydrophilic Coating (K152709)
Device Description

The Inno-Pathwire is a steerable guidewire available in a diameter of 0.014" (0.36 mm) and an effective length of 190 cm. The distal tip is shapeable. Before use, the tip can be shaped "J". The wire construction includes a stainless steel proximal shaft and a distal super-elastic nitinol shaft for flexibility and performance. The two shafts are connected by a super-elastic nitinol hypotube. The distal shaft is soldered with the tip coil or the tip coil and proximal coil both. For IW-14-190-EXS model, the distal shaft is soldered to the tip coil only but for IW-14-190-STS and IW-14-190-MDS, their distal shafts are soldered to the tip coil and proximal coil both. The tip coil is visible under X-ray to assist the physician with the movement of the guidewire. The distal segment of the guidewire, up to the hypotube, is coated with hydrophilic coating to reduce friction for improved guidewire movement within the catheter and arteries. The proximal end of the guidewire is coated with PTFE coating which reduces friction of the wire within a catheter.

The guidewire 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 for twisting and controlling the guidewire. The guidewires are packaged within a cardboard box which contains five individual guidewires.

Intended Use

The Inno-Pathwire is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA).

Principle of Operation

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

Substantial Equivalence

The Inno-Pathwire was found to be substantially equivalent to the HI-TORQUE BALANCE MIDDLEWEIGHT Guide Wires, Premarket Notification K152709. A comparison of the technological characteristics is summarized on the table below:
## Comparison of the Inno-Pathwire and Predicate Device

<table>
<thead>
<tr>
<th>Device Characteristic</th>
<th>New Device: Inno-Pathwire</th>
<th>Predicate: HI-TORQUE BALANCE MIDDLEWEIGHT Guide Wire</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indication for Use</td>
<td>To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA).</td>
<td>To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA).</td>
</tr>
</tbody>
</table>
| Materials              | • Proximal Shaft, Ribbon, Proximal coil:  
                          ▶ 304 stainless steel  
                          • Distal shaft, Hypotube:  
                          ▶ Nickel-Titanium alloy  
                          • Tip coil:  
                          ▶ Platinum - Tungsten alloy  
                          • Proximal of the guidewire coating:  
                          ▶ PTFE  
                          • Distal of the guidewire coating:  
                          ▶ Hydromer® Hydrophilic coating  
                          • Proximal Shaft, Ribbon, Proximal coil:  
                          ▶ 304 stainless steel  
                          • Distal shaft, Hypo tube:  
                          ▶ Nickel-Titanium alloy  
                          • Tip coil:  
                          ▶ Platinum-Nickel alloy  
                          • Proximal of the guidewire coating:  
                          ▶ PTFE  
                          • Distal of the guidewire coating:  
                          ▶ Pellathane hydrophilic coating |
| Diameter               | 0.014”                    | 0.014”                                               |
| Length                 | 190cm                     | 190cm                                                |
| Sterility              | Ethylene Oxide            | Irradiation                                          |
| Shelf - life           | Two Years                 | Two Years                                            |

The Inno-Pathwire is substantially equivalent to the HI-TORQUE BALANCE MIDDLEWEIGHT Guide Wire in technology / principal of operation is similar in the material and design. The main differences between the Inno-Pathwire device and the predicate device are the tip coil material and the hydrophilic coating material. These differences do not affect the intended use, safety or effectiveness of the Inno-Pathwire. Performance (bench) testing and biocompatibility testing were performed to demonstrate that the proposed device performs as intended and does not raise new questions of safety or efficacy compared to the predicate devices.
Non-Clinical Performance Testing

Performance testing has been conducted in accordance with FDA guidance document *Coronary and Cerebrovascular Guidewire Guidance, January 1995; Coronary, Peripheral, and Neurovascular Guidewire-Performance Tests and Recommended Labeling, Draft Guidance for Industry and Food and Drug Administration Staff, June 15, 2018; ISO 11070:2014, Sterile Single-use Intravascular Introducers, Dilators And Guidewires.* The results of the following performance tests have demonstrated substantial equivalence to the predicate device.

- Dimensional Verification and Visual Inspection
- Tensile Strength/Tip Pull
- Torque Strength
- Torqueability
- Coating Adherence/Integrity
- Particulate Evaluation
- Lubricity
- Resistance to corrosion
- Kink Resistance
- Tip Flexibility
- Radiopacity

Biocompatibility Testing

Biocompatibility testing was performed to ensure the material safety in accordance with the tests recommended in the *International Standard ISO 10993-1. “Biological Evaluation of Medical Devices Part-I: Evaluation and testing within a risk management process.”* The Inno-Pathwire 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-Pathwire:

- Cytotoxicity  ISO 10993-5
- Irritation and Skin Sensitization  ISO 10993-10
- Acute Systemic Toxicity  ISO 10993-11
- Pyrogenicity  ISO 10993-11
- SC5b-9 Complement Activation  ISO 10993-4
- Unactivated Partial Thromboplastin Time  ISO 10993-4
- Rabbit Blood Hemolysis  ASTM F756 /ISO 10993-4
- Hemocompatibility  ISO 10993-4
- Thrombogenicity  ISO 10993-4

The results obtained from the biological evaluation indicate that the products do not pose any safety risks associated with its introduction into the body and that materials selected for manufacture of these products are appropriate for the intended use.
**Sterilization**

Sterilization conditions have been validated in accordance with *ISO 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-Pathwire has been evaluated for non-endotoxin related factors. The rabbit pyrogen test was performed as described in ANSI/AAMI/ISO 10993-11. The results concluded that the Inno-Pathwire does not elicit a material mediated pyrogenic response. As a requirement for product release, finished product pyrogen testing is conducted on each manufacturing lot for commercial distribution as a requirement for product release. The test method used is the gel clot method for Bacterial Endotoxin Testing.

**Conclusion**

The Inno-Pathwire 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-Pathwire and the predicate device that raise new issues of safety and effectiveness.