DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 27, 2017

Asahi Intecc Co., Ltd.
℅ Candace Cederman
Senior Regulatory Affairs Consultant
Cardiomed Device Consultants, LLC
5523 Research Park Drive, Suite 205
Baltimore, Maryland 21228

Re: K162842
Trade/Device Name: Asahi PTCA Guide Wire Asahi SUOH 03
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: December 29, 2016
Received: December 30, 2016

Dear Ms. Cederman:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education 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. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

Fernando Aguel -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162842

Device Name
ASAHI® PTCA Guide Wire
ASAHI SUOH® 03

Indications for Use *(Describe)*
ASAHI PTCA Guide Wires are intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The ASAHI PTCA Guide Wires are not to be used in the neurovasculature.

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.

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510(k) Summary
[as required by 21 CFR 807.92(c)]

ASAHI® PTCA Guide Wire
ASAHI SUOH® 03
510(k) K162842

DATE PREPARED:	October 7, 2016
APPLICANT	ASAHI INTECC CO., LTD. 1703 Wakita-cho, Moriyama-ku Nagoya, Aichi 463-0024, Japan
CONTACT	Yoshi Terai President/CEO ASAHI INTECC USA, Inc. 2500 Red Hill Avenue, Suite 210 Santa Ana, CA 92705 Tel: (949) 756-8252, FAX: (949) 756-8165 e-mail: ASAHI.ra-fda@ASAHI-intecc.com
TRADE NAME:	ASAHI® PTCA Guide Wire • ASAHI SUOH® 03
DEVICE CLASSIFICATION:	Class 2 per 21 CFR §870.1330
CLASSIFICATION NAME:	Catheter, Guide, Wire
PRODUCT CODE	DQX- Catheter Guide Wire
PREDICATE DEVICES:	ASAHI® PTCA Guide Wire: • ASAHI® SION® blue (K122468) • ASAHI® SUOH® (K083904)
REFERENCE DEVICES:	ASAHI® PTCA Guide Wire: • ASAHI RG3 (K141339) ASAHI® Neurovascular Guide Wire: • ASAHI CHIKAI black, 300cm (K141751)

INTENDED USE/INDICATIONS FOR USE
ASAHI® PTCA GUIDE WIRE: ASAHI SUOH® 03

ASAHI PTCA Guide Wires are intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The ASAHI PTCA Guide Wires are not to be used in the neurovasculature.

DEVICE DESCRIPTION:

The ASAHI® PTCA Guide Wire: ASAHI SUOH® 03 consists of a core wire and a coil assembly. The coil assembly consists of an inner coil, safety wire, and an outer coil, soldered to the core wire. The distal portion of the coil is radiopaque so as to easily confirm its position under radioscopy. In addition, coatings are applied on the surface of ASAHI® PTCA Guide Wire: ASAHI SUOH® 03. The distal portion of the guidewire has a hydrophilic coating, and the proximal portion of the guidewire is coated with PTFE. The ASAHI® PTCA Guide Wire: ASAHI SUOH® 03 is available in various lengths and tip shapes. The shorter length device is designed for use with a commercially available Asahi Intecc extension wire.

COMPARISON WITH PREDICATE DEVICE:

Comparisons of the ASAHI® PTCA Guide Wire: ASAHI SUOH® 03 and predicate devices show that the technological characteristics of the Subject device such as the components, design, materials, sterilization method, shelf life and operating principle are identical or similar to the currently marketed predicate devices. The intended use of the Subject Device and its predicates are the same.

Name of Device	**ASAHI® PTCA Guide Wire: ASAHI SUOH 03**	**ASAHI® PTCA Guide Wire: ASAHI SUOH**	**ASAHI® PTCA Guide Wire: ASAHI SION blue**
510(k)	Current Application	K083904	K122468
Intended Use and Indications	intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The ASAHI PTCA Guide Wires are not to be used in the neurovasculature.	intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The Asahi SUOH PTCA Guide Wires are not to be used in the cerebral blood vessel.	intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The ASAHI PTCA GUIDE WIRES are not to be used in the cerebral blood vessels.
Target Body Location	Coronary and Peripheral		
Overall Lengths	190cm and 300cm	180cm and 300cm	180cm and 300cm
Nominal OD	0.014 in		
Outer Coil Material	Platinum-Nickel, Stainless Steel		
Core Wire Material	Stainless Steel		
Distal Coating	Hydrophilic coating		
Proximal Coating	PTFE		
Sterilization	Provided sterile via Ethylene Oxide to SAL10^{-6}		
Shelf Life	3 Years		

NON CLINICAL TESTING / PERFORMANCE DATA:

Non clinical laboratory testing was performed on the ASAHI® PTCA Guide Wire: ASAHI SUOH® 03 to determine substantial equivalence. The following testing/assessments were performed:

- Tensile Strength
- Torque Strength
- Torqueability
- Tip Flexibility
- Coating Adhesion/ Coating Integrity
- Catheter Compatibility
- Particulate Testing / Coating Integrity

The *in vitro* bench tests demonstrated that the ASAHI® PTCA Guide Wire: ASAHI SUOH® 03 met all acceptance criteria and performed similarly to the predicate devices. Performance data demonstrate that the device functions as intended, and has a safety and effectiveness profile that is similar to the predicate devices.

BIOCOMPATIBILITY:

The ASAHI® PTCA Guide Wire: ASAHI SUOH® 03 was compared to the predicate and reference devices. Based on similarities of the materials used in the subject device to its predicates / reference devices, the biocompatibility of the ASAHI® PTCA Guide Wire: ASAHI SUOH® 03 was verified to be the same as those of the predicates / reference devices.

CONCLUSION:

The ASAHI® PTCA Guide Wire: ASAHI SUOH® 03 has identical intended use and the same or similar technological characteristics such as components, design, materials, sterilization method, shelf life and operating principles as the predicate and reference devices. Performance data demonstrates that the device functions as intended.

Therefore, the ASAHI® PTCA Guide Wire: ASAHI SUOH® 03 is substantially equivalent to the predicate device.