DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 3, 2017

ASAHI INTECC CO., LTD.
% Candace Cederman
CardioMed Device Consultants, LLC
5523 Research Park Drive, Suite 205
Baltimore, Maryland 21228

Re: K163426
Trade/Device Name: ASAHI PTCA Guide Wires, ASAHI Peripheral Guide Wires, ASAHI Guide Wire Extension
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: March 1, 2017
Received: March 3, 2017

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,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K163426

Device Name
ASAHI PTCA Guide Wires, ASAHI Peripheral Guide Wires, ASAHI Guide Wire Extension

Indications for Use *(Describe)*

ASAHI PTCA Guide Wires:
ASAHI PTCA Guide Wires are intended to facilitate the placement of balloon dilation 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.

ASAHI Peripheral Guide Wires:
ASAHI Peripheral Guide Wires are intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is intended for peripheral vascular use only.

ASAHI Guide Wire Extension:
The ASAHI Guide Wire Extension accessory is intended for extension of the working length of an already introduced guide wire when exchanging over-the-wire interventional devices during an angioplasty procedure.

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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"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
(as required by 21 CFR 807.92)

ASAHI INTECC CO.,LTD.
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Tel. +81-52-768-1211 Fax. +81-52-768-1221
Branch offices: Tokyo, Nagoya, Osaka, Hong Kong, Amsterdam, Singapore, Beijing
Research Facilities and Factories: Osaka, Seto, Thailand, Hanoi

ASAHI PTCA Guide Wires
ASAHI Peripheral Guide Wires
ASAHI Guide Wire Extension

510(k) K163426

DATE PREPARED:	March 29, 2017
APPLICANT	ASAHI INTECC CO., LTD. 1703 Wakita-cho, Moriyama-ku Nagoya, Aichi 463-0024, Japan
CONTACT	Yoshinori Terai, President and 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 Wires ASAHI Peripheral Guide Wires ASAHI Guide Wire Extension
DEVICE CLASSIFICATION:	Class 2 per 21 CFR §870.1330
CLASSIFICATION NAME:	Catheter Guide Wire
PRODUCT CODE	DQX – Wire, Guide, Catheter
PREDICATE DEVICES:	• ASAHI PTCA Guide Wires (K022762, K031277, K032615, K041531, K043422, K052022, K052339, K062186. K063819, K072431, K072705, K083904, K100578, K101986, K122468, K122469, K133865, K153106) • ASAHI Peripheral Guide Wires (K061984, K071721, K083146, K103057, K110553, K150445, K153443) • ASAHI Guide Wire Extension (K083145, K101985)

INTENDED USE/INDICATIONS FOR USE

The intended use of these wires are unchanged:

ASAHI PTCA Guide Wires:

> *ASAHI PTCA Guide Wires are intended to facilitate the placement of balloon dilation 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.*

ASAHI Peripheral Guide Wires:

> *ASAHI Peripheral Guide Wires are intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is intended for peripheral vascular use only.*

ASAHI Guide Wire Extension

> *The ASAHI Guide Wire Extension accessory is intended for extension of the working length of an already introduced guide wire when exchanging over-the-wire interventional devices during an angioplasty procedure.*

DEVICE DESCRIPTION:

This modification details a change relating to the removal of perfluorooctanoic acid (PFOA) used by suppliers in the manufacture of PTFE (polytetrafluoroethylene) coating used on the ASAHI family of guidewires including ASAHI PTCA guide wires and ASAHI peripheral guidewires. All of these wires are steerable guide wires, constructed with a core wire with coil assembly. The distal ends of the guide wires have a radiopaque tip to achieve visibility. Various coatings are applied to the distal and proximal portions of the guidewires.

This submission covers the addition of an alternate type of PTFE coating material. The designs and performance of the guidewires are unchanged.

COMPARISON WITH PREDICATE DEVICES:

The technological characteristics of the subject guide wires are substantially equivalent to those of the predicate guidewires. The differences between the devices relates to the guide wire proximal coating. The guide wire design and indications remain unchanged.

Comparisons of the revised ASAHI guide wires to the predicate devices show that the technological characteristics of the Subject device such as the product performance, intended use/indications, components, materials, sterilization method, shelf life, manufacturing process, and operating principle are identical to the currently marketed predicate devices. The only difference is in the PTFE coating applied to the proximal portion of the device. The new PTFE is manufactured by a supplier without the use of PFOA.

Name of Device	**ASAHI PTCA Guide wire ASAHI Peripheral Guide wire ASAHI Guide wire Extension**	**ASAHI PTCA Guide wire ASAHI Peripheral Guide wire ASAHI Guide wire Extension**
510(k)	Current Application	Multiple
Intended Use and Indications	Unchanged	

Name of Device	ASAHI PTCA Guide wire ASAHI Peripheral Guide wire ASAHI Guide wire Extension	ASAHI PTCA Guide wire ASAHI Peripheral Guide wire ASAHI Guide wire Extension
Sterilization	Unchanged	
Shelf Life	Unchanged	
Target Body Location	Unchanged	
Outer Coil Material	Unchanged	
Core Wire Material	Unchanged	
Inner Coil Material	Unchanged	
Distal Tip Shape	Unchanged	
Overall length	Unchanged	
Outer coil length	Unchanged	
Outer Coil Outer Diameter	Unchanged	
Distal Outer Coating	Unchanged	
Proximal Coating	PTFE (with or without PFOA used in processing) Alternate PTFE (without PFOA used in processing)	PTFE (with or without PFOA used in processing)

NON CLINICAL TESTING / PERFORMANCE DATA:

Confirmatory non clinical laboratory testing was performed to determine substantial equivalence.

The following testing/assessments were performed:

Test	Test Method Summary	Results/Conclusions
Coating Adherence	Integrity of the coated core wire is determined before and after pretreatment and manipulation in excess of that expected in clinical use.	Test results confirmed that the coating adhesion was maintained during simulated clinical use in all test articles.
Coating Integrity & Particulate Characterization	Coating integrity and particulate generation were evaluated. The test samples were advanced through a clinically relevant simulated use model to the target location, retracted and the coating inspected under magnification. All particulate matter generated during insertion/retraction of the guidewire was characterized.	This testing characterized the coating integrity and particulate generation during simulated use. The test results confirmed that the coating integrity was maintained during simulated clinical use of the test articles.

The *in vitro* bench tests demonstrated that the devices with the modified coating 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:

Testing was performed to assess biocompatibility of the modified coating material.

Test	Test Method Summary	Results/Conclusions
Cytotoxicity	Testing was conducted in accordance with ISO 10993-5	Passed. No evidence of causing cell lysis or toxicity.
Intracutaneous Irritation	Testing was conducted in accordance with ISO 10993-10	Passed. Difference between test article and control less than 1.0.
Sensitization	Testing was conducted in accordance with ISO 10993-10	Passed. No evidence of causing delayed dermal contact sensitization
Systemic Toxicity	Testing was conducted in accordance with ISO 10993-11	Passed. No mortality or evidence of systemic toxicity
Material Mediated Pyrogenicity	Testing was conducted in accordance with ISO 10993-11, USP<151>	Passed. Test article judged as non-pyrogenic.
Hemocompatibility - Hemolysis	Testing was conducted in accordance with ISO 10993-4, ASTM F756	Passed. Hemolytic index was 0.0%.
Hemocompatibility – Complement Activation (SC5b-9, C3a)	Testing was conducted in accordance with ISO 10993-4	Passed. Test article is not considered to be a potential activator of the complement system.
Hemocompatibility – PTT	Testing was conducted in accordance with ASTM F2382	Passed. Test article is considered activator.
Hemocompatibility – in vivo Thromboresistance	Testing was conducted in accordance with ISO 10993-4	Passed. Test article is considered thromboresistant.

CONCLUSION:

The ASAHI guidewires with the alternate coating have the identical intended use and the same technological characteristics such as components, design, sterilization method, shelf life and operating principles as the predicate devices. Data demonstrate that the device performance is unchanged.

Therefore, the ASAHI guidewires are substantially equivalent to the predicate devices.