



July 5, 2018

Asahi Intecc Co., Ltd.  
% Candace Cederman  
Principal Consultant  
CardioMed Device Consultants, LLC  
3168 Braverton Street, Suite 200  
Edgewater, Maryland 21037

Re: K173277

Trade/Device Name: ASAHI® PTCA Guide Wire ASAHI SION black  
Regulation Number: 21 CFR 870.1330  
Regulation Name: Catheter Guide Wire  
Regulatory Class: Class II  
Product Code: DQX  
Dated: June 4, 2018  
Received: June 5, 2018

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.

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Gregory O'Connell  
2018.07.05 07:54:27 -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

510(k) Number (if known)  
K173277

Device Name  
ASAHI® PTCA Guide Wire ASAHI SION black

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.

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

**ASAHI® PTCA Guide Wire**  
**ASAHI SION black**  
**510(k) K173277**

<b>DATE PREPARED:</b>	July 2, 2018
<b>APPLICANT</b>	ASAHI INTECC CO., LTD. 3-100 Akatsuki-cho Seto, Aichi 489-0071, Japan
<b>CONTACT</b>	Yoshi Terai President/CEO ASAHI INTECC USA, Inc. 3002 Dow Ave, Suite 212 Tustin, CA 92780 Tel: (949) 756-8252, FAX: (949) 756-8165 e-mail: <a href="mailto:ASAHI.ra-fda@ASAHI-intecc.com">ASAHI.ra-fda@ASAHI-intecc.com</a>
<b>TRADE NAME:</b>	ASAHI® PTCA Guide Wire ASAHI SION black
<b>DEVICE CLASSIFICATION:</b>	Class 2 per 21 CFR §870.1330
<b>CLASSIFICATION NAME:</b>	Catheter, Guide, Wire
<b>PRODUCT CODE</b>	DQX- Catheter Guide Wire
<b>PREDICATE DEVICES:</b>	ASAHI® PTCA Guide Wire <ul style="list-style-type: none"> <li>• ASAHI® SION® (K163426)</li> </ul>
<b>REFERENCE DEVICES:</b>	ASAHI® PTCA Guide Wire <ul style="list-style-type: none"> <li>• ASAHI® SION® (K100578, K122469)</li> <li>• ASAHI® Fielder XT-A (K153106, K163426)</li> <li>• ASAHI® Fielder XT (K072431)</li> <li>• ASAHI® Fielder FC (K063819, K072705, K163426)</li> <li>• ASAHI® ULTIMATEbros 3 (K101986, K163426)</li> <li>• ASAHI® Gaia (K133865, K163426)</li> </ul> ASAHI® Neurovascular Guide Wire <ul style="list-style-type: none"> <li>• ASAHI CHIKAI black (K141751)</li> </ul>

**INTENDED USE/INDICATIONS FOR USE**  
**ASAHI® PTCA Guide Wire ASAHI SION black**

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 SION black 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 radiology. In addition, coatings are applied on the surface of the ASAHI® PTCA Guide Wire ASAHI SION black. The coil and distal portion of the guide wire are coated with polyurethane and then covered with hydrophilic coating. The proximal portion of the guide wire is coated with PTFE. The ASAHI® PTCA Guide Wire ASAHI SION black 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 SION black and predicate and reference 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 predicate/reference devices are the same.

Name of Device	ASAHI® PTCA Guide Wire ASAHI SION black	ASAHI® PTCA Guide Wire ASAHI SION	ASAHI® PTCA Guide Wire ASAHI Fielder XT-A
	Subject	Predicate	Reference
510(k)	K173277	K163426	K153106 K163426
Intended Use and Indications	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.	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.	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.
Target Location	Coronary and Peripheral vasculature		
Nominal OD	0.36mm (0.014 inch)		
Overall Lengths	190cm and 300cm	180cm and 300cm	190cm and 300cm
Outer Coil Material	Platinum-Nickel, Stainless Steel		Platinum-Nickel
Inner Coil Material	Stainless Steel		
Core Wire Material	Stainless Steel		
Undercoating	Polyurethane	NA	Polyurethane
Outer Distal Coating	Hydrophilic coating		
Proximal Coating	PTFE		
Sterilization	Provided sterile via Ethylene Oxide to SAL10 <sup>-6</sup>		
Shelf Life	3 years		

**NON CLINICAL TESTING / PERFORMANCE DATA:**

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

- Dimensional Verification
- Tensile Strength
- Torque Strength
- Torqueability
- Tip Flexibility
- Coating Adhesion
- Catheter Compatibility
- Coating Lubricity
- Radiopacity
- Particulate Testing / Coating Integrity

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

**BIOCOMPATIBILITY:**

The ASAHI® PTCA Guide Wire ASAHI SION black was compared to the predicate and reference devices. Based on similarities of the materials used in the subject device to its predicates / reference devices, biocompatibility testing of the ASAHI® PTCA Guide Wire ASAHI SION black was not completed.

**CONCLUSION:**

The ASAHI® PTCA Guide Wire ASAHI SION black 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 SION black is substantially equivalent to the predicate devices.