



Food and Drug Administration
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February 25, 2016

Asahi Intecc Co., Ltd.
% Ms. Candace Cederman
Senior Regulatory Affairs Consultant
CardioMed Device Consultants, LLC
5523 Research Park Drive, Suite 205
Baltimore, MD 21228

Re: K153443

Trade/Device Name: Asahi Astatto XS 40
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: November 25, 2015
Received: January 8, 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 yours,

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

Indications for Use

510(k) Number (if known)

K153443

Device Name

ASAHI Astato XS 40

Indications for Use (Describe)

This product is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is intended for peripheral vascular use only.

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 Astató XS 40

510(k) K153443

DATE PREPARED: February 2016

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APPLICANT	ASAHI Intecc Co., Ltd. 1703 Wakita-cho, Moriyama-ku Nagoya, Aichi 463-0024, Japan
OFFICIAL CORRESPONDENT	Carroll Councilman Sr. RA Manager 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 Astató XS 40
DEVICE CLASSIFICATION:	Class 2 per 21 CFR §870.1330
CLASSIFICATION NAME:	Catheter, Guide, Wire
PRODUCT CODE	DQX- Catheter Guide Wire
PREDICATE DEVICES:	Primary Predicate: ASAHI Astató XS 20 Peripheral Guide Wire (K103057) Secondary Predicate: ASAHI Astató 30 Peripheral Guide Wire (K071721) Reference Device: ASAHI RG3 (K141339)

INTENDED USE/INDICATIONS FOR USE

This product is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is intended for peripheral vascular use only.

DEVICE DESCRIPTION:

The ASAHI Atrato XS 40 Peripheral Guide Wire in this submission has a coil-type distal end. The coil is radiopaque to facilitate selection of the blood vessel and confirmation of the position of the guide wire's distal end by fluoroscopy. The core shaft surface is coated with Polytetrafluoroethylene (PTFE). The distal end is coated with a hydrophilic coating. The ASAHI Atrato XS 40 guide wires in this submission have an overall length range of 200 to 300 cm and a nominal outer diameter of 0.36 mm.

COMPARISON WITH PREDICATE DEVICES:

Comparisons of the ASAHI Atrato XS 40 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/indications between the Subject Device and its primary predicates are identical. There are specific design features of the Subject device that are similar to the primary predicate but not identical. Additional predicate devices have been used to demonstrate equivalence for these similar features.

Name of Device	ASAHI Peripheral Guide Wire • ASAHI Atrato XS 40	• Atrato XS 20 • Atrato 30
510(k)	Current Application	K103057 K071721
Intended Use and Indications	This product is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is intended for peripheral vascular use only.	
Sterilization	Provided sterile via Ethylene Oxide to SAL10 ⁻⁶	
Shelf Life	3 Years	
Target Body Location	Peripheral	
Outer Distal Hydrophilic coating	Yes	
Proximal Coating	PTFE	
Overall Length	200-300 cm	180-300 cm
Nominal OD	0.36 mm (0.014in) with tapered end	Atrato XS 20: 0.36 mm (0.014in) with tapered end Atrato 30: 0.45 mm (0.018in) with tapered end
Outer Coil Material	Platinum-Nickel	
Core Wire Material	Stainless Steel	

NON CLINICAL TESTING / PERFORMANCE DATA:

Non clinical laboratory testing was performed on the ASAHI Atrato XS 40 to determine substantial equivalence. The following testing/assessments were performed:

- Tensile Strength
- Torque Strength

- Torqueability
- Tip Flexibility (compared to secondary predicate, ASAHI Astatto 30)
- Coating Adhesion/Integrity
- Catheter Compatibility

The *in vitro* bench tests demonstrated that the ASAHI Astatto XS 40 met all acceptance criteria and performed similarly to the predicate devices. Performance data demonstrate that the device functions as intended, and is substantially equivalent to the predicate devices.

BIOCOMPATIBILITY:

The ASAHI Astatto XS 40 was compared to the primary predicate device and to the reference device ASAHI PTCA Guide Wire RG3. Based on the similar intended use, as well as the similarities of the materials and manufacturing methods used in the subject device and its predicate/reference devices, no additional biocompatibility testing of the ASAHI Astatto XS 40 was conducted.

CONCLUSION:

The ASAHI Astatto XS 40 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 devices. Performance data demonstrates that the device functions as intended.

Therefore, the ASAHI Astatto XS 40 is substantially equivalent to the predicate devices.