DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 21, 2016

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

Re: K153106
Trade/Device Name: Asahi Fielder XT-A, ASAHI Fielder XT-R
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: May 9, 2016
Received: May 10, 2016

Dear Candace 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 and Part 809); 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 and Part 809), 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

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)*

K153106

Device Name

ASAHI Fielder XT-A, ASAHI Fielder XT-R

Indications for Use *(Describe)*

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.

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 Wires
ASAHI Fielder XT-A
ASAHI Fielder XT-R

510(k) K153106

DATE PREPARED:	October 16, 2015
APPLICANT	ASAHI Intecc Co., Ltd. 1703 Wakita-cho, Moriyama-ku Nagoya, Aichi 463-0024, Japan
OFFICIAL CORRESPONDENT	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 Wires: • ASAHI Fielder XT-A • ASAHI Fielder XT-R
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 Wire ASAHI Gaia First (K133865) ASAHI PTCA Guide Wire ASAHI Fielder FC (K063819, K072705) ASAHI PTCA Guide Wire ASAHI Fielder XT (K072431)

INTENDED USE/INDICATIONS FOR USE

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.

DESCRIPTION:

As a basic structure, the Fielder XT-A, Fielder XT-R, consists of a taper core wire and 2 types coils (a tapered outer coil and an inner rope coil). The taper core wire and the coils are soldered together. The coil is radiopaque so as to easily confirm its position under radioscopy.

The coil and distal part of tapered core wire of the products are coated with polyurethane and then covered with hydrophilic polymer. The proximal end of the tapered core wire is coated with PTFE.

The nominal outer diameter of both the Fielder XT-A and Fielder XT-R is 0.36mm, with a distal diameter of 0.26mm. Both the Fielder XT-A and Fielder XT-R are available in 190cm and 300cm, total length. The tip shape is straight.

COMPARISON WITH PREDICATE DEVICES:

Comparisons of the Fielder XT-A and Fielder XT-R and predicate devices show that the technological characteristics of the Subject devices 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 the same as the primary predicates.

Name of Device	**ASAHI Fielder XT-A ASAHI Fielder XT-R**	**ASAHI Gaia First**	**ASAHI Fielder FC ASAHI Fielder XT**
510(k)	Current Application	K133865	K063819, K072705 K072431
Intended Use and Indications	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.		
Sterilization	Provided sterile via Ethylene Oxide to $SAL10^{-6}$		
Shelf Life	3 Years		
Target Body Location	Coronary and Peripheral		
Inner coil	Yes		No
Undercoating	Polyurethane	NA	Polyurethane
Outer Distal coating	Hydrophilic		
Proximal Coating	PTFE		
Overall Length	190, 300 cm		180, 300 cm (FC) 190, 300 cm (XT)
Nominal OD	0.36 mm (0.014 inches)		
Outer Coil Material	Platinum-Nickel		Platinum-Nickel and Stainless Steel (FC), Platinum-Nickel (XT)
Core Wire Material	Stainless Steel		

NON CLINICAL TESTING / PERFORMANCE DATA:

Non clinical laboratory testing was performed on the ASAHI Fielder XT-A and ASAHI Fielder XT-R to determine substantial equivalence. The following testing/assessments were performed:

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

The *in vitro* bench tests demonstrated that the ASAHI Fielder XT-A and ASAHI Fielder XT-R met 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 Fielder XT-A and ASAHI Fielder XT-R were compared to the predicate devices. Based on similarities of the materials used in the subject device to its predicates, the biocompatibility of the ASAHI Fielder XT-A and ASAHI Fielder XT-R was verified to be the same as those of the predicates.

CONCLUSION:

The ASAHI Fielder XT-A and ASAHI Fielder XT-R have identical intended uses 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 devices function as intended.

Therefore, the ASAHI Fielder XT-A and ASAHI Fielder XT-R are substantially equivalent to the predicate devices.