February 12, 2018

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

Re: K171933
Trade/Device Name: ASAHI PTCA Guide Wires (ASAHI Gaia First, Gaia Second, Gaia Third; ASAHI Fielder XT; ASAHI Fielder XT-A, Fielder XT-R; ASAHI Miraclebros3, Miraclebros4.5, Miraclebros6, Miraclebros12; ASAHI Ultimate bros3, ASAHI Confianza; ASAHI Confianza Pro, Confianza Pro 12), ASAHI Corsair Microcatheter, ASAHI Corsair Pro Microcatheter
Regulation Number: 21 CFR 870.1330; 21 CFR 870.1250
Regulation Name: Catheter Guide Wire; Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQX; DQY
Dated: January 9, 2018
Received: January 11, 2018

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); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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)*

K171933

Device Name

ASAHI® PTCA Guide Wire
•ASAHI Gaia First, Gaia Second, Gaia Third, •ASAHI Fielder XT, •ASAHI Fielder XT-A, Fielder XT-R, •ASAHI Miraclebros3, Miraclebros4.5, Miraclebros6, Miraclebros12, •ASAHI Ultimate bros3, •ASAHI Confianza, •ASAHI Confianza Pro, Confianza Pro 12

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), including use in crossing or assisting in crossing de novo coronary chronic total occlusions (CTO).

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

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)*

K171933

Device Name
- ASAHI Corsair Microcatheter
- ASAHI Corsair Pro Microcatheter

Indications for Use *(Describe)*

This product is intended to provide support to facilitate the placement of guide wires in the coronary and peripheral vasculatures, and can be used to exchange one guide wire for another.

This product is also intended to assist in the delivery of contrast media into the coronary, peripheral and abdominal vasculatures, and to assist in crossing de novo coronary chronic total occlusions (CTO).

This device should not be used in neurovasculature.

Type of Use *(Select one or both, as applicable)*

[X] 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® Corsair® / ASAHI® Corsair® Pro Microcatheter
510(k) K171933

DATE PREPARED:	June 26, 2017
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 Gaia First, Gaia Second, Gaia Third • ASAHI Fielder XT • ASAHI Fielder XT-A, Fielder XT-R • ASAHI MIRACLEbros 3, MIRACLEbros 4.5, MIRACLEbros 6, MIRACLEbros 12 • ASAHI ULTIMATEbros 3 • ASAHI Confianza • ASAHI Confianza Pro, Confianza Pro 12 ASAHI® Corsair® / ASAHI® Corsair® Pro Microcatheter • ASAHI Corsair • ASAHI Corsair Pro
DEVICE CLASSIFICATION:	Class 2 per 21 CFR §870.1330 – Guide wires Class 2 per 21 CFR §870.1250 - Catheter
CLASSIFICATION NAME:	Catheter guide wire Percutaneous catheter
PRODUCT CODE	DQX – Wire, Guide, Catheter DQY – Catheter, Percutaneous
PREDICATE DEVICES:	ASAHI® PTCA Guide Wire • ASAHI Gaia First, Gaia Second, Gaia Third (K133865) • ASAHI Fielder XT (K072431) • ASAHI Fielder XT-A, Fielder XT-R (K153106) • ASAHI MIRACLEbros 3, MIRACLEbros 4.5, MIRACLEbros 6 (K022762, K031277) • ASAHI MIRACLEbros 12 (K052339) • ASAHI ULTIMATEbros 3 (K101986) • ASAHI Confianza (K022762, K031277) • ASAHI Confianza Pro (K041531) • ASAHI Confianza Pro 12 (K052339)

	ASAHI® Corsair® / ASAHI Corsair® Pro Microcatheter • ASAHI Corsair (K083127, K151103) • ASAHI Corsair Pro (K161126)

INTENDED USE/INDICATIONS FOR USE

ASAHI PTCA Guide Wires:

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), including use in crossing or assisting in crossing de novo coronary chronic total occlusions (CTO).

The ASAHI PTCA Guide Wires are not to be used in the neurovasculature.

ASAHI Corsair Microcatheter / ASAHI Corsair Pro Microcatheter:

This product is intended to provide support to facilitate the placement of guide wires in the coronary and peripheral vasculatures, and can be used to exchange one guide wire for another.

This product is also intended to assist in the delivery of contrast media into the coronary, peripheral and abdominal vasculatures, and to assist in crossing de novo coronary chronic total occlusions (CTO).

This device should not be used in neurovasculature.

DEVICE DESCRIPTION:

The ASAHI® PTCA Guide Wires and ASAHI® Corsair® / ASAHI® Corsair® Pro Microcatheters covered by this submission are existing marketed devices. There have been no physical changes to the subject devices as compared to the currently marketed predicate devices except for a change in indication and related clinical information added to the labeling. The designs and performance of the guidewires are unchanged.

The ASAHI® PTCA Guide Wires consist of a core wire and a coil assembly. Depending on the model, the coil assembly could consist of an outer coil soldered to the core wire, or an inner coil and an outer coil, with or without a safety wire, 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 Wires. The coil and distal portion of the guidewire have a hydrophilic outer coating. The proximal portion of the guidewires are coated with PTFE. The ASAHI® PTCA Guide Wires are available in various lengths and tip shapes. The shorter length devices are designed for use with a commercially available Asahi Intecc extension wire.

The ASAHI Corsair / ASAHI Corsair Pro Microcatheter consists of a distal tip and a shaft tube that are inserted into a vascular connector for catheter control and infusion of contrast media. No accessories are part of this device. The ASAHI Corsair has a radiopaque marker coil that is imbedded into the inner layer of resin to facilitate the tip location during angiographic procedures. In addition, the devices have a hydrophilic coating on the outer surface of the shaft tube to provide a smooth transition in blood vessels. The distal tip of the ASAHI Corsair / ASAHI

Corsair Pro has a tapered shape and is designed to have increased flexibility towards the distal end. PTFE is applied to the inner lumen of the catheters for the purposes of a smooth transition and exchange of guidewires.

The microcatheters also contain wires to reinforce the distal tip and shaft tube to allow the physician greater control of the device during interventional procedures.

COMPARISON WITH PREDICATE DEVICE:

The devices included in this submission are unchanged from the predicate devices. The technological characteristics of the Subject devices such as the components, design, materials, sterilization method, shelf life and operating principle are identical to the currently marketed predicate devices. This submission covers only the inclusion of additional language in the Indications for Use.

Name of Device	**ASAHI PTCA Guide wire**	**ASAHI PTCA Guide wire (Predicate)**
510(k)	Current Application	K022762, K031277, K041531, K052339, K072431, K101986, K133865, K153106
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), including use in crossing or assisting in crossing de novo coronary chronic total occlusions (CTO). 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.
Sterilization	Identical	
Shelf Life	Identical	
Target Body Location	Identical	
Outer Coil Material	Identical	
Core Wire Material	Identical	
Inner Coil Material	Identical	
Distal Tip Shape	Identical	
Overall length	Identical	
Outer coil length	Identical	
Outer Coil Outer Diameter	Identical	
Distal Outer Coating	Identical	
Proximal Coating	Identical	

Name of Device	ASAHI Corsair Microcatheter ASAHI Corsair Pro Microcatheter	ASAHI Corsair Microcatheter ASAHI Corsair Pro Microcatheter
510(k)	Current Application	K083127, K151103, K161126
Intended Use and Indications	This product is intended to provide support to facilitate the placement of guide wires in the coronary and peripheral vasculatures, and can be used to exchange one guide wire for another. This product is also intended to assist in the delivery of contrast media into the coronary, peripheral and abdominal vasculatures, and to assist in crossing de novo coronary chronic total occlusions (CTO). This device should not be used in neurovasculature.	The ASAHI Corsair is intended to provide support to facilitate the placement of guide wires in the coronary and peripheral vasculature, and can be used to exchange one guide wire for another. The ASAHI Corsair is also intended to assist in the delivery of contrast media in the coronary, peripheral, and abdominal vasculature. The ASAHI Corsair Pro is intended to provide support to facilitate the placement of guide wires in the coronary and peripheral vasculature, and can be used to exchange one guide wire for another. The ASAHI Corsair Pro is also intended to assist in the delivery of contrast media in the coronary, peripheral, and abdominal vasculature. This device should not be used in neurovasculature.
Sterilization	Identical	
Shelf Life	Identical	
Target Body Location	Identical	
Overall length	Identical	
Nominal Outer Diameter	Identical	
Coating Length	Identical	
Distal Tip Outer Diameter	Identical	
Distal Tip Inner Diameter	Identical	
Shaft Tube Outer Diameter	Identical	
Shaft Tube Inner Diameter	Identical	
Materials	Identical	

NON CLINICAL TESTING – PERFORMANCE DATA / BIOCOMPATIBILITY / PACKAGING AND STERILIZATION TESTING:

There have been no physical changes to the subject devices as compared to the predicate devices. Comparisons of bench, biocompatibility, packaging, and sterilization testing are not necessary. The subject and predicate devices are identical and bench testing, biocompatibility, packaging, and sterilization for the subject devices are therefore substantially equivalent to their respective predicate devices.

CLINICAL TESTING:

A prospective, multi-center, single-arm study of 163 subjects was performed to evaluate the safety and effectiveness of the ASAHI series of Guide Wires and/or Corsair Microcatheter (study devices) in patients with symptomatic ischemic heart disease attributed to a chronic total occlusion (CTO) in a native coronary artery. The primary objective of the trial was to evaluate placement of any guide wire beyond the CTO in the true vessel lumen in subjects in which at least one of the

study devices were used. Procedure success was defined as (1) angiographic visualization of any guide wire crossing the target lesion and (2) absence of in-hospital major adverse cardiac events (MACE), defined as any serious adverse experience that includes cardiac death, target lesion revascularization, or post-procedural myocardial infarction (MI). For this study the definition of MI also included any CK-MB reading > 3xULN.

Primary Endpoint Results and Analysis

The procedure success rate for this study was 73.0% (p=0.0044). The Investigators successfully re-canalized the vessel in 89.0% of procedures. The absence of in-hospital MACE was 81.0%. Study success was defined as meeting the primary endpoint of a successful re-canalization rate and absence of in-hospital MACE above 63.1% with a one-sided lower 95% confidence bound of 67.3%. A summary of primary endpoint procedure success is provided in the table below.

Parameter	Result	Two-Sided 95% CI	Performance Goal	Lower Bound of One-Sided 95% CI	P-value
Procedure Success	73.0% (119/163)	(66.2%, 79.8%)	63.1%	67.3%	0.0044
Successful re-canalization	89.0% (145/163)	---	---	---	---
Absence of in-hospital MACE	81.0% (132/163)	---	---	---	---

Repeating this same data, using the criteria for a clinically relevant MI as recommended in the Expert Consensus Document from the Society for Cardiovascular Angiography and Interventions (SCAI) published in 2013.

Parameter	Result	Two-Sided 95% CI	Performance Goal	Lower Bound of One-Sided 95% CI	P-value
Procedure Success	84.7% (138/163)	(79.1%, 90.2%)	63.1%	80.0%	<0.0001
Successful re-canalization	89.0% (145/163)	---	---	---	---
Absence of in-hospital MACE	93.9% (153/163)	---	---	---	---

CONCLUSION:

The results of this clinical trial demonstrate that the study ASAHI PTCA Guide Wires, including the Gaia Series, Fielder XT, Fielder XT-A, Fielder XT-R, MIRACLEbros Series, ULTIMATEbros 3, Confianza, and Confianza Pro Series, and the ASAHI Corsair Microcatheter, exceeded the pre-specified safety and effectiveness performance criteria for crossing CTOs and re-canalizing the target vessel in this subject population. The primary and secondary endpoints of the study

were met. The data support a CTO indication for these wires. No new safety or effectiveness issues were raised during the study, and therefore, the ASAHI® PTCA Guide Wires and ASAHI® Corsair® Microcatheter are substantially equivalent to the predicate devices.