DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 4, 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: K152249
Trade/Device Name: ASAHI Corsair Armet
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 9, 2016
Received: February 11, 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

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 on last page.

510(k) Number *(if known)*
K152249

Device Name
ASAHI Corsair Armet

Indications for Use *(Describe)*
The ASAHI Corsair Armet is intended to provide support to facilitate the placement of guide wires in the peripheral vasculature, and can be used to exchange one guide wire for another.

The ASAHI Corsair Armet is also intended to assist in the delivery of contrast media into the peripheral vasculature.

This device should not be used in coronary vasculature or neuro vasculature.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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 Corsair Armet

510(k) 152249

DATE PREPARED:	February 25, 2016
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 Corsair Armet
DEVICE CLASSIFICATION:	Class 2 per 21 CFR §870.1250
CLASSIFICATION NAME:	Percutaneous Catheter
PRODUCT CODE	DQY- Catheter, Percutaneous
PREDICATE DEVICES:	**Primary Predicates:** ASAHI Corsair Microcatheter (K151103) **Reference Devices:** ASAHI Fubuki 043 (K141981) ASAHI Tornus Support Catheter (K051772) ASAHI PTCA Guide Wire Marker Wire (K022762)

INTENDED USE/INDICATIONS FOR USE

The ASAHI Corsair Armet is intended to provide support to facilitate the placement of guide wires in the peripheral vasculature, and can be used to exchange one guide wire for another.

The ASAHI Corsair Armet is also intended to assist in the delivery of contrast media into the peripheral vasculature.

This device should not be used in coronary vasculature or neuro vasculature.

DESCRIPTION:

The ASAHI Corsair Armet consists of a distal tip, a shaft tube that is inserted into vasculature, a protector, and a connector for catheter control and infusion of contrast media. The device has a hydrophilic coating on the outer surface of distal tip and the shaft tube to provide a smooth transition in blood vessels. The distal tip of the Corsair Armet has a tapered shape. PTFE is applied to the inner lumen of the catheter for the purposes of a smooth transition and exchange of guidewires.

COMPARISON WITH PREDICATE DEVICES:

Comparisons of the ASAHI Corsair Armet and predicate devices show that the technological characteristics of the ASAHI Corsair Armet 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 of the Subject Device are a subset of the primary predicates. There are specific design features of the Subject device that are similar to the primary predicate but not identical. Additional reference devices have been used to demonstrate equivalence for these similar features.

Name of Device	**ASAHI Corsair Armet**	**ASAHI Corsair Microcatheter**
510(k)	Current Application	K151103
Intended Use and Indications	The ASAHI Corsair Armet is intended to provide support to facilitate the placement of guide wires in the peripheral vasculature, and can be used to exchange one guide wire for another. The ASAHI Corsair Armet is also intended to assist in the delivery of contrast media into the peripheral vasculature. This device should not be used in coronary vasculature or neuro vasculature.	The ASAHI Corsair Microcatheter 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. The Corsair Microcatheter is also intended to assist in the delivery of contrast media into the coronary, peripheral, and abdominal vasculatures.
Sterilization	Provided sterile via Ethylene Oxide to SAL10^{-6}	
Target Body Location	Peripheral	Peripheral, Coronary
Hydrophilic coating	Yes	
Effective Length	600-1500 mm	900 - 1500mm
Nominal OD	Distal : 0.75mm Proximal : 0.83 mm	Distal : 0.75mm Proximal : 1.0mm
Catheter Shaft Material	Polyamide-elastomer	Polyamide-elastomer
Single Use	Yes	

NON CLINICAL TESTING / PERFORMANCE DATA:

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

- Appearance/Dimensions
- Corrosion Resistance
- Force at Break
- Liquid Leakage under Pressure
- Air Leakage
- Leak and Damage under High Static Pressure
- Radio-Detectability
- Torque Transmission
- Slide Durability
- Kink Resistance
- Torque Durability

The *in vitro* bench tests demonstrated that the ASAHI Corsair Armet 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 Corsair Armet was compared to the predicate devices. Based on similarities of the materials used in the subject device to its predicates and reference devices, the biocompatibility of the ASAHI Corsair Armet was verified to be the same as those of the predicates and reference devices.

CONCLUSION:

The ASAHI Corsair Armet has identical intended use, a subset of the indications, 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 Corsair Armet is substantially equivalent to the predicate devices.