



Food and Drug Administration
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June 14, 2016

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

Re: K161362

Trade/Device Name: Asahi Corsair Armet
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: May 13, 2016
Received: May 16, 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)

K161362

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 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)



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ASAHI Corsair Armet

510(k) K161362

DATE PREPARED:	May 13, 2016
APPLICANT	Asahi Intecc Co., Ltd. 1703 Wakita-cho, Moriyama-ku Nagoya, Aichi 463-0024, Japan
CONTACT	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 Corsair Armet
DEVICE CLASSIFICATION:	Class 2 per 21 CFR §870.1250
CLASSIFICATION NAME:	Percutaneous Catheter
PRODUCT CODE	DQY – Catheter, Percutaneous
PREDICATE DEVICES:	ASAHI Corsair Armet (K152249)

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 neurovasculature.

DEVICE 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.

The primary change in this Special 510(k) involves a minor change in the shape of the distal tip.

COMPARISON WITH PREDICATE DEVICES:

Comparisons of the modified ASAHI Corsair Armet to its predicate device show that the technological characteristics of the Subject device such as the product performance, intended use/indications, components, materials, sterilization method, shelf life, manufacturing process, and operating principle are identical to the currently marketed predicate devices. There are only minor dimensional variations between the Subject and predicate device.

Name of Device	ASAHI Corsair Armet	ASAHI Corsair Armet
510(k)	Current Application	K152249
Intended Use and Indications	<p>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.</p> <p>The ASAHI Corsair Armet is also intended to assist in the delivery of contrast media into the peripheral vasculature.</p> <p>This device should not be used in coronary vasculature or neurovasculature.</p>	
Target Body Location	Peripheral	
Hydrophilic coating	Yes	
Effective Length	600-1500 cm	
Nominal Outer Diameter	Distal : 0.75mm Proximal : 0.83 mm	
Catheter Shaft Material	Polyamide-elastomer	
Distal Tip Length	1.2mm	2.0mm
Single Use	Yes	
Sterilization	Provided sterile via Ethylene Oxide to SAL10 ⁻⁶	
Shelf Life	3 Years	

NON CLINICAL TESTING / PERFORMANCE DATA:

Confirmatory non clinical laboratory testing was performed on the modified 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 modified 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 modified ASAHI Corsair Armet was compared to the predicate device. Based on the identical materials and manufacturing process used in the subject device to its predicate, the biocompatibility of the modified ASAHI Corsair Armet was verified to be the same as those of the predicate.

CONCLUSION:

The modified ASAHI Corsair Armet 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 modified ASAHI Corsair Armet is substantially equivalent to the predicate device.