



Food and Drug Administration
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June 23, 2015

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

Re: K151103
Trade/Device Name: ASAHI Corsair Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: April 23, 2015
Received: April 24, 2015

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,



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)

K151103

Device Name

ASAHI Corsair Microcatheter

Indications for Use (Describe)

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.

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 Corsair Microcatheter
510(k) K151103

DATE PREPARED:	April 29, 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 Corsair Microcatheter
DEVICE CLASSIFICATION:	Class 2 per 21 CFR §870.1250
CLASSIFICATION NAME:	Percutaneous Catheter
PRODUCT CODE	DQY
PREDICATE DEVICE:	ASAHI Corsair Microcatheter (K083127)

INTENDED USE/INDICATIONS FOR USE

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.

DESCRIPTION:

The ASAHI Corsair 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 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 device has a hydrophilic coating on the outer surface of the shaft tube to provide a smooth transition in blood vessels. The distal tip of the Corsair has a tapered shape and is designed to have increased flexibility towards the distal end. PTFE is applied to the inner lumen of the catheter for the purposes of a smooth transition and exchange of guidewires.

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

COMPARISON WITH PREDICATE DEVICES:

Comparisons of the ASAHI Corsair Microcatheter and predicate device 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 currently marketed predicate devices. The addition of a shorter length catheter does not raise any new questions of safety or effectiveness.

The intended use/indications between the Subject Device and its primary predicate are identical.

Name of Device	ASAHI Corsair Microcatheter	ASAHI Corsair Microcatheter
510(k)	Current Application	K083127
Indications for Use	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.	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	Provided sterile via Ethylene Oxide to SAL10 ⁻⁶
Shelf Life	2 Years	2 Years
Overall Length	90 cm / 135 cm/ 150 cm	135 cm/ 150 cm
Nominal OD	0.93 mm	0.93 mm
Coating Length	600 mm	600 mm
Coating material	Hydrophilic	Hydrophilic

NON CLINICAL TESTING / PERFORMANCE DATA:

Non clinical laboratory testing was performed on the ASAHI Corsair Microcatheter to determine substantial equivalence. Torque durability testing was conducted to ensure that the shorter length of the ASAHI Corsair Microcatheter maintained the torque durability within the acceptance criteria. Coating integrity/peel testing confirmed equivalent performance of the Subject device as compared to its predicate. Confirmatory biocompatibility testing was done to ensure that the minor modifications to the coating materials had no negative impact upon biocompatibility of the device.

The *in vitro* bench test demonstrated that the ASAHI Corsair Microcatheter met all acceptance criteria and performed similarly to the predicate devices. Performance data demonstrate that the Subject device functions as intended and is substantially equivalent to the predicate device.

BIOCOMPATIBILITY:

The ASAHI Corsair Microcatheter was compared to the predicate and reference devices. The ratios of the coating material were modified slightly from the ASAHI Corsair Microcatheter predicate but are the same as used on the reference ASAHI Fubuki (K141981). Confirmatory testing (cytotoxicity, sensitization, intracutaneous reactivity, systemic toxicity (acute), and hemocompatibility) supports that the modifications to the coating material continue to render the device biocompatible.

CONCLUSION:

The ASAHI Corsair Microcatheter 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 Corsair Microcatheter is substantially equivalent to the predicate device.