



Food and Drug Administration  
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August 25, 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: K161126

Trade/Device Name: ASAHI Corsair Pro  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II  
Product Code: DQY  
Dated: July 26, 2016  
Received: July 27, 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); 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,

A handwritten signature in black ink, appearing to read "Bram Zuckerman", is written over a large, light gray watermark of the FDA logo. The word "for" is printed in a small, black, sans-serif font directly beneath the signature.

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)

K161126

Device Name

ASAHI Corsair Pro

Indications for Use (Describe)

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 into the coronary, peripheral, and abdominal vasculature. This device should not be used in 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(c)]

#### ASAHI Corsair Pro Microcatheter

#### 510(k) 161126

<b>DATE PREPARED:</b>	July 26, 2016
<b>APPLICANT</b>	ASAHI Intecc Co., Ltd. 1703 Wakita-cho, Moriyama-ku Nagoya, Aichi 463-0024, Japan
<b>CONTACT</b>	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: <a href="mailto:ASAHI.ra-fda@ASAHI-intecc.com">ASAHI.ra-fda@ASAHI-intecc.com</a>
<b>TRADE NAME:</b>	ASAHI Corsair Pro
<b>DEVICE CLASSIFICATION:</b>	Class 2 per 21 CFR §870.1250
<b>CLASSIFICATION NAME:</b>	Percutaneous Catheter
<b>PRODUCT CODE</b>	DQY- Catheter, Percutaneous
<b>PREDICATE DEVICES:</b>	ASAHI Corsair Microcatheter (K151103, K083127)

#### INTENDED USE/INDICATIONS FOR USE

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 into the coronary, peripheral, and abdominal vasculature. This device should not be used in neurovasculature.

#### DESCRIPTION:

The ASAHI Corsair Pro consists of a distal tip and a shaft tube that are inserted into a vascular connector for catheter control and infusion of contrast media. 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 Pro has a tapered shape and is designed to have increased flexibility towards the distal end. The inner lumen of the catheter is PTFE 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 Pro 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 minor differences between the Subject and predicate devices do not raise any new questions of safety or effectiveness.

The intended use/indications between the Subject Device and its primary predicate are identical except of last sentence has been added for clarity.

Name of Device	ASAHI Corsair Pro	ASAHI Corsair Microcatheter
510(k)	Current Application	K083127, K151103
Indications for Use	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 into the coronary, peripheral, and abdominal vasculature. This device should not be used in neurovasculature.	The ASAHI Corsair Microcatheter 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 Corsair Microcatheter is also intended to assist in the delivery of contrast media into the coronary, peripheral, and abdominal vasculature.
Sterilization	Provided sterile via Ethylene Oxide to SAL10 <sup>-6</sup>	
Target body location	Peripheral, Coronary	
Shelf Life	3 Years	
Overall Length	135 cm/ 150 cm	90 cm / 135 cm/ 150 cm
Nominal OD	0.93 mm	0.93 mm
Coating Length	600 mm	
Coating material	Hydrophilic	
Marker?	No	Yes
Single use	Yes	

#### NON CLINICAL TESTING / PERFORMANCE DATA:

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

- Appearance/Dimensions
- Radio-Detectability
- Slide Durability
- Kink Resistance
- Force at Break
- Flexibility
- Torque Transmission
- Liquid Leakage under Pressure

- Leak and Damage under High Static Pressure
- Air Leakage
- Corrosion Resistance
- Torque Durability

The *in vitro* bench tests demonstrated that the ASAHI Corsair Pro 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 Pro was compared to the predicate devices. All of materials used for the ASAHI Corsair Pro are identical to the ASAHI Corsair Microcatheter predicate except that there is no marker in the Subject device.

**CONCLUSION:**

The ASAHI Corsair Pro has identical intended use, similar indications, and the same or similar technological characteristics such as components, design, materials, sterilization method, shelf life, performance, and operating principles as the predicate devices. Performance data demonstrates that the device functions as intended.

Therefore, the ASAHI Corsair Pro is substantially equivalent to the predicate devices.