



January 22, 2016

Asahi Intecc Co. Ltd.
c/o Candace Cederman
CardioMed Device Consultants LLC
5523 Research Park Drive, Suite 205
Baltimore, MD 21228

Re: K152447

Trade/Device Name: Asahi Caravel
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: December 18, 2015
Received: December 22, 2015

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" (21CFR 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)

K152447

Device Name

ASAHI Caravel

Indications for Use (Describe)

This 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.

This microcatheter is also intended to assist in the delivery of contrast media into the coronary and peripheral vasculatures.

Do not use this microcatheter other than for use in the coronary and peripheral 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.

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:

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Traditional 510(k) Premarket Notification
ASAHI Caravel



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510(k) Summary
[as required by 21 CFR 807.92(c)]

ASAHI Caravel

510(k) K152447

DATE PREPARED:	August 26, 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 Caravel
DEVICE CLASSIFICATION:	Class 2 per 21 CFR §870.1250
CLASSIFICATION NAME:	Percutaneous Catheter
PRODUCT CODE	DQY- Catheter, Percutaneous
PREDICATE DEVICES:	ASAHI Corsair Microcatheter (K151103)

INTENDED USE/INDICATIONS FOR USE

This 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.

This microcatheter is also intended to assist in the delivery of contrast media into the coronary and peripheral vasculatures.

Do not use this microcatheter other than for use in the coronary and peripheral vasculatures.

DESCRIPTION:

The ASAHI Caravel 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 Caravel 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 Caravel and predicate devices show that the technological characteristics of the ASAHI Caravel 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 Caravel	ASAHI Corsair Microcatheter
510(k)	Current Application	K151103
Intended Use and Indications	This 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. This microcatheter is also intended to assist in the delivery of contrast media into the coronary and peripheral vasculatures. Do not use this microcatheter other than for use in the coronary and peripheral 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	
Target Body Location	Peripheral, Coronary	Coronary, Peripheral Abdominal (contrast media only)
Hydrophilic coating	Yes	
Effective Length	1350 – 1500 mm	900 - 1500mm
Nominal OD	Distal : 0.62mm, Proximal : 0.85 mm	Distal : 0.75mm, Proximal : 1.0mm
Catheter Shaft Mat'l	Polyamide Polyamide-elastomer Polyurethane	Polyamide-elastomer

NON CLINICAL TESTING / PERFORMANCE DATA:

Non clinical laboratory testing was performed on the ASahi Caravel 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
- Slide Durability
- Kink Resistance
- Shaft Flexibility

The *in vitro* bench tests demonstrated that the ASahi Caravel 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 Caravel was tested in accordance with ISO 10993, and found to be biocompatible. The following tests were performed:

Cytotoxicity

- Intracutaneous Study
- Sensitization
- Systemic Toxicity
- Hemolysis
- In Vivo Thromboresistance
- Partial Thromboplastin Time
- C3a Complement Activation
- Sc5b-9 Complement Activation
- USP Pyrogen

CONCLUSION:

The ASahi Caravel 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 Caravel is substantially equivalent to the predicate devices.