June 22, 2019

Asahi Intecc Co., Ltd.
% Candace Cederman
Principal Consultant
CardioMed Device Consultants, LLC
1783 Forest Drive #254
Annapolis, Maryland 21401

Re: K182844
Trade/Device Name: ASAHI SASUKE
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: May 22, 2019
Received: May 24, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Kenneth Cavanaugh, Ph.D.
Director (Acting)
DHT2C: Division of Coronary
and Peripheral Interventional Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182844

Device Name
ASAHI® SASUKE®

Indications for Use *(Describe)*

This product is intended to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary arterial vasculature and peripheral vessels, to facilitate placement of guidewires and other interventional devices, for use during two guidewire procedures, and to subselectively infuse/deliver diagnostic or therapeutic agents. Not for use in the 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.

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 SASUKE®

510(k) K182844

DATE PREPARED:	June 21, 2019
APPLICANT	ASAHI INTECC CO., LTD. 1703 Wakita-cho, Moriyama-ku Nagoya, Aichi 463-0024, Japan
CONTACT	Yoshi Terai President/CEO ASAHI INTECC USA,INC. 3002 Dow Avenue, Suite 212 Tustin, CA 92780 Tel: (949) 756-8252, FAX: (949) 756-8165 e-mail: ASAHI.ra-fda@ASAHI-intecc.com
TRADE NAME:	ASAHI SASUKE®
DEVICE CLASSIFICATION:	Class 2 per 21 CFR §870.1250
CLASSIFICATION NAME:	Percutaneous Catheter
PRODUCT CODE	DQY- Catheter, Percutaneous
PREDICATE DEVICE:	Twin-Pass Dual Access Catheter (K060327)
REFERENCE DEVICE	ASAHI Caravel (K152447)

INDICATIONS FOR USE FOR THE ASAHI SASUKE®

This product is intended to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary arterial vasculature and peripheral vessels, to facilitate placement of guidewires and other interventional devices, for use during two guidewire procedures, and to subselectively infuse/deliver diagnostic or therapeutic agents. Not for use in the neurovasculature.

DESCRIPTION:

The ASAHI SASUKE® Dual Lumen Catheter is a sterile single use device designed for use in the arterial vasculature. The ASAHI SASUKE® is a catheter that has two lumens: an over-the-wire lumen that extends across the length of the catheter, and a rapid exchange lumen installed at the distal end. This product consists of a tip, shaft, protector and connector. The surface of the distal section of the shaft of this product is coated with hydrophilic coating. In addition, a radiopaque

marker is provided between the tip and the shaft of the product, enabling the user to view the position of the tip under X-ray fluoroscopy. The device packaging includes a needle to flush the lumens prior to use.

COMPARISON WITH PREDICATE DEVICES:

Comparisons of the ASAHI SASUKE® and predicate device show that the technological characteristics of the Subject device such as the design, materials, sterilization method, and operating principle are similar to currently marketed predicate devices. The minor differences between the Subject and predicate device do not raise any new questions of safety or effectiveness.

The indications for use between the Subject Device and its primary predicate are the same.

Name of Device	**ASAHI SASUKE®**	**Twin-Pass Dual Access Catheter**
510(k)	Current Application	K060327
Indications for Use	This product is intended to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary arterial vasculature and peripheral vessels, to facilitate placement of guidewires and other interventional devices, for use during two guidewire procedures, and to subselectively infuse/deliver diagnostic or therapeutic agents. Not for use in the neurovasculature.	The Twin-Pass catheter is intended to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement and exchange of guidewires and other interventional devices, for use during two guidewire procedures and to subselectively infuse/deliver diagnostic or therapeutic agents.
Sterilization	Provided sterile via Ethylene Oxide	Same
Sterility Assurance Level	$SAL10^{-6}$	Same
Effective Length	145cm	135 cm
Guidewire Compatibility	0.014" (0.36mm)	Same
Outer Diameter (shaft)	1.05mm (proximal) 1.08mm (distal)	0.97mm, 1.14 mm (proximal) 1.19mm, 1.35 mm (distal)
Outer Diameter (tip)	Tapered from 0.50 to 0.72mm	0.66mm
Distal Coating	Hydrophilic	Same
Single Use	Yes	Same
Radiopaque?	Yes, with Marker Band	Same

NON CLINICAL TESTING / PERFORMANCE DATA:

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

- Appearance/Dimensions
- Corrosion Resistance

- Force at Break
- Liquid Leakage under Pressure
- Air Leakage
- Radio-Detectability
- Slide Durability
- Kink Resistance
- Particulate and Coating Integrity testing

The *in vitro* bench tests demonstrated that the ASAHI SASUKE® met all acceptance criteria. Performance data demonstrate that the device functions as intended, and is substantially equivalent to the predicate and reference devices.

BIOCOMPATIBILITY:

The ASAHI SASUKE® was tested in accordance with ISO 10993, and found to be biocompatible. The following tests were performed:

- Cytotoxicity
- Intracutaneous
- Sensitization
- Systemic Toxicity
- USP Pyrogen
- Hemolysis
- Sc5b-9 Complement Activation
- In Vivo Thrombogenicity
- Partial Thromboplastin Time
- Platelet and Leukocyte Binding

CONCLUSION:

The ASAHI SASUKE® has the same intended use and indications, and the same or similar technological characteristics such as design, materials, sterilization method, performance, and operating principles as the predicate and reference devices. Performance data demonstrates that the device functions as intended.

Therefore, the ASAHI SASUKE® is substantially equivalent to the predicate and reference devices.