December 20, 2018

Asahi Intecc Co., Ltd.
% Candace Cederman
Principal Consultant
Cardiomed Device Consultants, LLC
3168 Braverton Street, Suite 200
Edgewater, Maryland 21037

Re: K182420
Trade/Device Name: ASAHI Corsair Pro® XS
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 14, 2018
Received: November 19, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lydia S. Glaw -S

Digitally signed by Lydia S. Glaw -S
Date: 2018.12.20 14:35:02 -05'00'

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K182420

Device Name
ASAHI Corsair Pro® XS

Indications for Use *(Describe)*
This product 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 product is also intended to assist in the delivery of contrast media into the coronary, peripheral and abdominal vasculatures, and to assist in crossing de novo coronary total occlusions (CTO).

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.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
(as required by 21 CFR 807.92)

3-100 Akatsuki-cho, Seto, Aichi 489-0071 Japan
Tel. +81-561-48-5551 Fax. +81-561-48-5552
Branch office: Tokyo, Nagoya, Osaka, Hong Kong, EU, Singapore, Beijing, India, Middle Eastern
Research Facilities and Factories: Osaka, Seto, Thailand, Hanoi

ASAHI Corsair Pro XS

510(k) K182420

DATE PREPARED:	December 14, 2018
APPLICANT	ASAHI INTECC CO., LTD. 3-100 Akatsuki-cho, Seto, Aichi 489-0071 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 Corsair Pro® XS
DEVICE CLASSIFICATION:	Class 2 per 21 CFR §870.1250
CLASSIFICATION NAME:	Percutaneous Catheter
PRODUCT CODE	DQY – Catheter, Percutaneous
PREDICATE DEVICE:	ASAHI Corsair Pro® (K171933)
REFERENCE DEVICE:	ASAHI Caravel (K152447)

INTENDED USE/INDICATIONS FOR USE

This product 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 product is also intended to assist in the delivery of contrast media into the coronary, peripheral and abdominal vasculatures, and to assist in crossing de novo coronary total occlusions (CTO).

This device should not be used in neurovasculature.

DEVICE DESCRIPTION:

The ASAHI Corsair Pro® XS 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 ASAHI Corsair Pro® XS 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.

As compared to the predicate device, the primary change presented in this 510(k) involves a minor change in the dimensions of the tip and catheter shaft and the structure of inner layer (rope coil) of the catheter shaft.

COMPARISON WITH PREDICATE DEVICE:

Comparisons of the ASAHI Corsair Pro® XS 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 device. The minor differences between the subject and predicate device do not raise any new questions of safety or effectiveness

Name of Device	ASAHI Corsair Pro®	ASAHI Corsair Pro® XS
510(k)	K171933	Current Application
Intended Use and Indications	This product 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 product is also intended to assist in the delivery of contrast media into the coronary, peripheral and abdominal vasculatures, and to assist in crossing de novo coronary chronic total occlusions (CTO). This device should not be used in neurovasculature.	
Target Body Location	Coronary and Peripheral	
Hydrophilic coating	Yes	
Effective Length	1350 mm, 1500 mm	
Nominal Outer Diameter	Tapered 0.3 mm to 1.0 mm	Tapered 0.44 mm to 0.95 mm
Catheter Shaft Material	Polyamide elastomer & Polyamide	
Distal Tip Length	5 mm	6.5 mm
Single Use	Yes	
Sterilization	Provided sterile via Ethylene Oxide to SAL10^{-6}	
Shelf Life	3 years	

NON CLINICAL TESTING / PERFORMANCE DATA:

Based on a risk analysis to assess the impact of the modification on the device, ASAHI INTECC performed the following confirmatory non-clinical testing on the ASAHI Corsair Pro® XS to determine substantial equivalence.

The following testing/assessments were performed:

- Appearance / Dimensional testing
- Tensile strength
- Corrosion resistance
- Liquid leakage under pressure
- Air leakage into hub assembly during aspiration

- Pressure Resistance (Burst pressure)
- Radio-detectability
- Torque durability
- Slide durability (Lubricity)
- Kink resistance
- Torque transmission
- Flexibility

The *in vitro* bench tests demonstrated that the ASAHI Corsair Pro® XS 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® XS was compared to the predicate device. Based on the comparison of materials and manufacturing process used in the subject device to its predicate, the biocompatibility of the ASAHI Corsair Pro® XS was verified to be the same as the predicates.

The following tests were performed:

- Cytotoxicity
- Sensitization
- Intracutaneous Irritation
- Systemic Toxicity
- USP Rabbit Pyrogen, Material Mediated
- Hemolysis
- Partial Thromboplastin Time
- In Vivo Thromboresistance
- Sc5b-9 Complement Activation

CONCLUSION:

The ASAHI Corsair Pro® XS 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 device. Performance data demonstrates that the device functions as intended.

Therefore, the ASAHI Corsair Pro® XS is substantially equivalent to the predicate device.