November 29, 2019

Asahi Intecc Co., Ltd.
Cynthia Valenzuela
Director, Regulatory Affairs
3002 Dow Avenue, Suite 212
Tustin, California 92780

Re: K192782
Trade/Device Name: ASAHI CROSSWALK Peripheral Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: September 30, 2019
Received: September 30, 2019

Dear Cynthia Valenzuela:

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 Lydia Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention 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)*
K192782

Device Name
ASAHI CROSSWALK™ Peripheral Support Catheter

Indications for Use *(Describe)*
The CROSSWALK™ Peripheral Support Catheter is intended to provide support to facilitate the placement of guide wires in the peripheral vasculature, and can be used to exchange one guide wire for another. The CROSSWALK™ Peripheral Support Catheter is also intended to assist in the delivery of contrast media into the peripheral vasculature.

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 21CFR§807.92(c)]

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ASAHI CROSSWALK™ Peripheral Support Catheter

510(K) K192782

DATE PREPARED:	30SEP2019
APPLICANT:	ASAHI INTECC CO., LTD 3-100 Akatsuki-cho, Seto Aichi 489-0071, Japan
PRIMARY CONTACT:	**Mrs. Cynthia Valenzuela** **Director, Regulatory Affairs** **ASAHI INTECC USA, INC.** **3002 Dow Avenue, Suite 212** **Tustin, California 92780** **Phone: (714) 442 0575** **Fax: (949) 377 3255** Email: cynthiav@asahi-intecc-us.com
TRADE NAME:	ASAHI CROSSWALK™ Peripheral Support Catheter
DEVICE CLASSIFICATION:	Class II, 21CFR§870.1250
CLASSIFICATION NAME:	Percutaneous Catheter
PRODUCT CODE:	DQY, Catheter, Percutaneous
PREDICATE DEVICE(S):	**Primary Predicate:** ASAHI Corsair Armet (K161362)

Intended Use/Indications for Use

The CROSSWALK™ Peripheral Support Catheter is intended to provide support to facilitate the placement of guide wires in the peripheral vasculature, and can be used to exchange one guide wire for another. The CROSSWALK™ Peripheral Support Catheter is also intended to assist in the delivery of contrast media into the peripheral vasculature.

Device Description:

The ASAHI CROSSWALK™ Peripheral Support Catheters (PSC) are a single lumen catheter with a three layer construction that is composed of a braid reinforced polymer shaft over a PTFE liner. The catheter also has a proximal female hub, a distal radiopaque atraumatic tip, hydrophilic coating and tungsten loaded radiopaque markers on the distal outer surface of the catheter.

There are three sizes in the family, a 0.035", 0.018" and 0.014" guidewire compatible models, whereas the 0.018" and 0.014" models are designed to fit into the 0.035" model for additional proximal support.

Comparison with Predicate Device:

A comparison of the ASAHI CROSSWALK™ Peripheral Support Catheter and predicate devices show that the technological characteristics of the ASAHI CROSSWALK™ such as 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 predicate. There are specific design features of the Subject Device that are similar to the predicate which has demonstrated equivalence for these similar features.

Name of Device	ASAHI Corsair Armet	ASAHI CROSSWALK™
510(K)	K161362	Current Application
Intended Use and Indications	The ASAHI Corsair Armet is intended to provide support to facilitate the placement of guide wires in the peripheral vasculature, and can be used to exchange one guide wire for another. The ASAHI Corsair Armet is also intended to assist in the delivery of contrast media into the peripheral vasculature. This device should not be used in coronary vasculature or neurovasculature.	The CROSSWALK™ is intended to provide support to facilitate the placement of guide wires in the peripheral vasculature, and can be used to exchange one guide wire for another. The CROSSWALK™ is also intended to assist in the delivery of contrast media into the peripheral vasculature.
Target Body Location	Peripheral	
Hydrophilic Coating	Yes	
Effective Length	600-1500mm	900-1700mm
Nominal Outer Diameter	Distal: 0.75mm Proximal: 0.83mm	Distal 014: 0.0285in (0.724mm) 018: 0.0330in (0.838mm) 035: 0.0550in (1.397mm) Proximal 014: 0.0350in (0.889mm) 018: 0.0350in (0.889mm) 035: 0.0550in (1.397mm)

Catheter Shaft Material	Polyamide-elastomer	Polyamide/Polyamide-elastomer
Distal Tip Length	1.2mm	1.0cm (10mm)
Single Use	Yes	
Sterilization	Ethylene Oxide	
SAL	10^{-6}	
Shelf life	3 Years	1 Year

NON CLINICAL TESTING / PERFORMANCE DATA;

Non Clinical Laboratory testing was performed on the ASAHI CROSSWALK™ Peripheral Support Catheter to determine substantial equivalence. The following tests were performed:

- Visual Inspection
- Corrosion Resistance
- Force Break
- Liquid Leak
- Air Leak
- Radio-Detectability
- Torque Transmission
- Torque Durability
- Slide Durability
- Kink Resistance
- Flow Test
- Dimensions
- Coating Integrity

In the *in vitro* bench tests demonstrated that the ASAHI CROSSWALK™ Peripheral Support Catheter met all acceptance criteria and performed similarly to the predicate devices. Performance data demonstrates that the device functions as intended, and is substantially equivalent to the predicate devices.

All bench testing of the ASAHI CROSSWALK™ Peripheral Support Catheter was performed on finished sterilized product. The acceptance criteria were based on ISO10555-1. Tests not conducted per ISO10555-1 were conducted using in-house validated procedures with internally developed acceptance criteria.

All ASAHI CROSSWALK™ Peripheral Support Catheter test samples met the acceptance criteria for each of the tests listed in this submission. There were no deviations from the acceptance criteria. Testing shows that the ASAHI CROSSWALK™ Peripheral Support Catheter is equivalent to the predicate ASAHI Corsair Armet.

BIOCOMPATIBILITY:

The Biological Safety of the ASAHI CROSSWALK™ Peripheral Support Catheter was verified in accordance with the ISO10993-1, Biological Evaluation of Medical Devices. The testing was performed by independent laboratories. The results provided assurance that the peripheral support catheters have a safe biocompatibility profile.

CONCLUSION:

The ASAHI CROSSWALK™ Peripheral Support Catheter has identical intended use, the same 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 CROSSWALK™ Peripheral Support Catheter is substantially equivalent to the predicate device.