September 8, 2020

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

Re: K202252
Trade/Device Name: ASAHI Corsair Armet 18
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: July 31, 2020
Received: August 10, 2020

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)*
K202252

Device Name
ASAHI Corsair Armet 18

Indications for Use *(Describe)*
The ASAHI Corsair Armet 18 is intended to provide support to facilitate the placement of guidewires in the peripheral vasculature, and can be used to exchange one guide wire for another.

The ASAHI Corsair Armet 18 is also intended to assist in the delivery of contract media into the peripheral vasculature.

This device should not be used in coronary vasculature or 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
K202252

In accordance with the Safety Medical Devices Act of 1990 (SMDA), a 510(K) Summary of safety and effectiveness information upon which this substantial equivalence determination is based, is provided in this section.

DATE PREPARED:	31JUL2020
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 Corsair Armet 18
DEVICE CLASSIFICATION:	Class II, 21CFR§870.1250
CLASSIFICATION NAME:	Percutaneous Catheter
PRODUCT CODE:	DQY, Catheter, Percutaneous
PREDICATE DEVICE(S):	ASAHI Corsair Armet (K161362)

Intended Use/Indications for Use

The ASAHI Corsair Armet 18 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 18 is also intended to assist in the delivery of contract media into the peripheral vasculature.

This device should not be used in coronary vasculature or neurovasculature.

Device Description:

This product consists of a distal tip, a shaft tube, a protector and a connector. The distal tip and distal side of shaft are coated with hydrophilic coating on the outer surface. The tip is radiopaque, and the distal end is clearly distinguished by the tip.

Comparison with Predicate Device:

A comparison of the ASAHI Corsair Armet 18 Microcatheter and predicate device shows that the technological characteristics of the ASAHI Corsair Armet 18 Microcatheter such as components, design, materials, sterilization method, shelf life and operating principle are identical or similar to the currently marketed predicate device.

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 Corsair Armet
510(K)	(K161362)	Subject Device / 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 contract media into the peripheral vasculature. This device should not be used in coronary vasculature or neurovasculature.	The ASAHI Corsair Armet 18 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 18 is also intended to assist in the delivery of contract media into the peripheral vasculature. This device should not be used in coronary vasculature or neurovasculature.
Target Body Location	Peripheral	
Hydrophilic Coating	Yes	
Effective Length	600-1500cm	600-1350cm
Nominal Outer Diameter	Distal: 0.75mm Proximal: 0.83mm	Distal: 0.73mm Proximal: 0.87mm
Catheter Shaft Material	Polyamide-elastomer	
Distal Tip Length	1.2mm	1.50mm
Single Use	Yes	
Sterilization	Ethylene Oxide to SAL^{-6}	
Shelf life	3 Years	

NON-CLINICAL TESTING / PERFORMANCE DATA;

Non Clinical Laboratory testing performed on the ASAHI Corsair Armet 18 Microcatheter to determine substantial equivalence:

- Air Leakage
- Appearance / Dimensions
- Burst Pressure Under Static Condition
- Corrosion Resistance
- Kink Resistance
- Liquid Leakage Under Pressure
- Radio-Detectability
- Slide Durability
- Tensile Strength / Force at Break
- Torque Durability
- Torque Transmission

In the *in vitro* bench tests demonstrated that the ASAHI Corsair Armet 18 Microcatheter 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 device.

All bench testing of the ASAHI Corsair Armet 18 Microcatheter performed on finished sterilized product. The acceptance criteria is based on ISO10555-1. Tests not conducted per ISO10555-1 were completed using in-house validated procedures with internally developed acceptance criteria.

All ASAHI Corsair Armet 18 Microcatheter 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 Corsair Armet 18 Microcatheter is equivalent to the predicate ASAHI Corsair Armet.

BIOCOMPATIBILITY:

The Biological Safety test of the ASAHI Corsair Armet 18 Microcatheter was not required, as the subject device did not change in material from its predicate device deeming biocompatibility testing unnecessary.

CONCLUSION:

The ASAHI Corsair Armet 18 Microcatheter has substantial 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 Corsair Armet 18 Microcatheter is considered, substantially equivalent to the predicate device.