June 25, 2024

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

Re: K241158
Trade/Device Name: ASAHI Veloute; ASAHI Veloute C3; ASAHI Tellus; ASAHI Tellus C3
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: April 25, 2024
Received: April 26, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Samuel G. Raben -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241158

Device Name
ASAHI Veloute, ASAHI Veloute C3, ASAHI Tellus, ASAHI Tellus C3

Indications for Use *(Describe)*
This microcatheter is a medical device intended for angiography and/or infusion of various substances including diagnosis, embolization and treatment in the peripheral vasculature using an appropriate guide catheter and guide wire. The microcatheter is not intended for use in neurovasculature, coronary arteries and carotid arteries.

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 Veloute, ASAHI Veloute C3
ASAHI Tellus, ASAHI Tellus C3
510(k) K241158

DATE PREPARED:	April 25, 2024
APPLICANT	ASAHI INTECC CO., LTD. 3-100 Akatsuki-cho, Seto Aichi 489-0071 Japan
CONTACT	Mrs. Cynthia Valenzuela Director, Quality Systems, Regulatory Affairs/Compliance ASAHI INTECC USA, INC. 3002 Dow Ave, Suite 212 Tustin, CA 92780 USA Phone: (714) 442 0575 Fax: (949) 377 3255 Email: cynthiav@asahi-intecc-us.com
TRADE NAME:	ASAHI Veloute, ASAHI Veloute C3 ASAHI Tellus, ASAHI Tellus C3
DEVICE CLASSIFICATION:	Class II per 21 CFR §870.1250
CLASSIFICATION NAME:	Percutaneous Catheter
PRODUCT CODE	DQY
PREDICATE DEVICE:	Excelsior SL-10 (K013789)
REFERENCE DEVICE:	Echelon Micro Catheter (K031992) Renegade STC 18 (K023681) Headway Duo Microcatheter (K120917) ASAHI FUBUKI 043 and ASAHI FUBUKI (K141981)

INDICATIONS FOR USE:

This microcatheter is a medical device intended for angiography and/or infusion of various substances including diagnosis, embolization and treatment in the peripheral vasculature using an appropriate guide catheter and guide wire. The microcatheter is not intended for use in neurovasculature, coronary arteries and carotid arteries.

DESCRIPTION:

The ASAHI Veloute, ASAHI Veloute C3, ASAHI Tellus and ASAHI Tellus C3 Microcatheters are sterile single use devices designed for use in the peripheral vasculature. The ASAHI Veloute, ASAHI Veloute C3, ASAHI Tellus and ASAHI Tellus C3 consist of a catheter shaft that is reinforced with braid wires to enhance pushability and maintain patency of the inner lumen. A radiopaque marker is fixed on the distal end of the catheter shaft to facilitate location of the catheter during angiography. The distal portion of the catheter shaft is flexible and available in two shapes, straight and angled, to provide improved trackability in tortuous vessels. A hydrophilic coating is applied on the outer surface of the catheter to provide a smooth transition.

In addition, accessories, including either a stylet, syringe and RHV (rotating hemostasis valve), or a stylet, syringe, inserter and hemostasis valve are available for use with the ASAHI Veloute, ASAHI Veloute C3, ASAHI Tellus and ASAHI Tellus C3.

COMPARISON WITH PREDICATE DEVICES:

Comparisons of the ASAHI Veloute, ASAHI Veloute C3, ASAHI Tellus and ASAHI Tellus C3 to the predicate and reference 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 and reference device do not raise any new questions of safety or effectiveness.

The indications for use of the subject device are a subset of that of its primary predicate.

Comparison with Predicate Device

Name of Device	ASAHI Veloute ASAHI Veloute C3	ASAHI Tellus ASAHI Tellus C3	Excelsior SL-10
510(k)	K241158		K013789
Classification Regulation	21 CFR 870.1250		21 CFR 870.1250
Common Name	Percutaneous Catheter		Percutaneous Catheter
Product Code	DQY		DQY
Classification Regulation	21 CFR 870.1250		21 CFR 870.1250
Indications for Use	This microcatheter is a medical device intended for angiography and/or infusion of various substances including diagnosis, embolization and treatment in the peripheral vasculature using an appropriate guide catheter and guide wire. The microcatheter is not intended for use in neurovasculature, coronary arteries and carotid arteries.		The Excelsior SL-10 Microcatheter is intended to assist in the delivery of diagnostic agents, such as contract media, and therapeutic agents, such as occlusion coils, into the peripheral, coronary and neurovasculature.
Max Guide Wire Diameter	OD: 0.41 mm (0.016“)		OD: 0.36mm (0.014”)
Guide catheter Compatibility	Minimum ID: 1.05mm (0.041”) (Veloute, Tellus) 0.85mm (0.033”) (Veloute C3, Tellus C3)		Minimum ID: 1.00mm (0.038”)
Effective Length	105, 125, 150cm		150cm
Shaft Tube Outer Diameter	Distal 0.58mm (1.7Fr, 0.023”) Proximal 0.94mm (2.8Fr, 0.037”) Proximal(C3) 0.80mm (2.4Fr, 0.031”)	Distal 0.63mm (1.9Fr, 0.025”) Proximal 0.94mm (2.8Fr, 0.037”) Proximal(C3) 0.80mm (2.4Fr, 0.031”)	Distal 0.60mm (1.7Fr, 0.023”) Proximal 0.80mm (2.4Fr, 0.031”)
Tip Shape	Straight, Angle		Straight Pre-Shaped 45 Pre-Shaped 90 Pre-Shaped J Pre-Shaped C Pre-Shaped S
Distal Coating	Hydrophilic		Hydrophilic
Radiopaque	Yes		Yes
Single Use	Yes		Yes
Sterilization	Provided sterile via Ethylene Oxide		Provided sterile via Ethylene Oxide

NON CLINICAL TESTING / PERFORMANCE DATA:

Non clinical laboratory testing was performed on the ASAHI Veloute, ASAHI Veloute C3, ASAHI Tellus and ASAHI Tellus C3 to determine substantial equivalence. The following testing/assessments were performed:

Test	Result
Appearance/Dimensions/Tip Shape	Pass
Corrosion resistance	Pass
Peak tensile Strength	Pass
Tip Flexibility	Pass
Liquid leakage	Pass
Radio-detectability	Pass
Air Leakage	Pass
Burst Pressure	Pass
Flow Rate	Pass
Power Injection	Pass
Kink Resistance	Pass
Slidability	Pass
Connector	Pass
Coat integrity / Particulate Evaluation in a clinically relevant model	This testing is for characterization only.
Torque Strength	Pass

The *in vitro* bench tests demonstrated that the ASAHI Veloute, ASAHI Veloute C3, ASAHI Tellus and ASAHI Tellus C3 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 Tellus was tested in accordance with ISO 10993, and found to be biocompatible. The following tests were performed:

Test Method	Standard	Acceptance Criteria	Results
Cytotoxicity MEM Elution Test	ISO 10993-5 No deviations	The test system is considered suitable if no signs of cellular reactivity (Grade 0) are noted for both the negative control article and the medium control.	Non-cytotoxic
Sensitization KLIGMAN Maximization Test	ISO 10993-10 No deviations	The extracts should show no evidence of causing delayed dermal contact sensitization in the guinea pig.	Non-Sensitizing
Irritation Intracutaneous Injection Test	ISO 10993-10 No deviations	The test extract and the negative control must exhibit similar edema and erythema scores.	Non-Irritant
Systemic Toxicity Acute Systemic Toxicity Test	ISO 10993-11 No deviations	The test article must not show significantly greater biological activity than the control.	No Systemic Toxicity
Systemic Toxicity Rabbit Pyrogen Test (material mediated)	ISO 10993-11 No deviations	The test article should not increase the rectal temperature of any of the animals by more than 0.5 degrees Celsius.	Non-pyrogenic
Hemocompatibility Rabbit Blood Hemolysis Test	ISO 10993-4 No deviations	Test article in direct contact with blood and test article extract must be non-hemolytic.	Non-hemolytic
Hemocompatibility Unactivated Partial Thromboplastin Time Test	ISO 10993-4 No deviations	The UPTT of the plasma exposed to test article extract should not significantly decreased when compared to untreated and negative controls.	Minimal activator
Hemocompatibility Complement Activation Assay (SC5b-9)	ISO 10993-4 No deviations	The plasma exposed to test article must exhibit no significant increase in SC5b-9 when compared to activated NHS and negative control after 60 minutes exposure.	Not an Activator
Hemocompatibility Thrombogenicity Study in Dogs	ISO 10993-4 No deviations	Compare results of test article to predicate control for Thrombogenic response. Determine acceptability of results as part of risk management.	Thromboresistant

STERILIZATION AND SHELF LIFE:

The ASAHI Veloute, ASAHI Veloute C3, ASAHI Tellus and ASAHI Tellus C3 sterilization process using Ethylene Oxide (EO) has been validated in accordance with ISO 11135: 2014 to achieve a sterility assurance level (SAL) of 10^{-6}. EO and Ethylene Chlorohydrin (ECH) residuals were below the limits specified in ISO 10993-7:2008.
Bacterial Endotoxin Levels were below the level of 20 EU/device.
Both baseline and accelerated shelf-life testing were conducted demonstrating the device will perform as intended to support the proposed 3 year shelf-life.

CONCLUSION:

The ASAHI Veloute, ASAHI Veloute C3, ASAHI Tellus and ASAHI Tellus C3 have the similar 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 device. Performance data demonstrates that the device functions as intended.