May 11, 2026

ASAHI INTECC CO., LTD.
% Ariel Barrett, PhD
Associate Director of Regulatory Affairs
ASAHI INTECC USA, Inc.
22 Executive Park, Suite 110
Irvine, California 92614

Re: K254178
Trade/Device Name: SAYA 86 Radial Access Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP
Dated: April 9, 2026
Received: April 9, 2026

Dear Ariel Barrett:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

NAIRA MURADYAN -S

Naira Muradyan, PhD
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K254178

Device Name
SAYA 86 Radial Access Guide Catheter

Indications for Use *(Describe)*
The SAYA 86 Radial Access Guide Catheter is indicated for the introduction of interventional devices into 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.

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

ASAHI INTECC CO.,LTD.
Global Headquarters and R&D Center
3-100 Akatsuki-cho, Seto-shi, Aichi 489-0071 Japan
TEL : +81-561-48-5551 FAX : +81-561-48-5552
http://www.asahi-intecc.co.jp/

SAYA 86 Radial Access Guide Catheter

510(k) K254178

Date Prepared:	May 8, 2026
Applicant:	ASAHI INTECC CO., LTD. 3-100 Akatsuki-cho, Seto, Aichi 489-0071 Japan
Contact:	Dr. Ariel Barrett Associate Director of Regulatory Affairs ASAHI INTECC USA, Inc. 22 Executive Park, Suite 110 Irvine, CA 92614 Tel: 240-429-9335 e-mail: ariel.barrett@asahi-intecc-us.com
Device Name:	SAYA 86 Radial Access Guide Catheter
Device Classification:	Class II, 21 CFR § 870.1250
Regulation Name:	Percutaneous Catheter
Product Code:	QJP- Percutaneous Catheter, Neurovasculature
Predicate Device:	Rist™ 079 Radial Access Guide Catheter (K241388)
Reference Device:	FUBUKI XF Neurovascular Long Sheath (K213589)

Indications For Use

The SAYA 86 Radial Access Guide Catheter is indicated for the introduction of interventional devices into the neurovasculature.

Device Description

The SAYA 86 Radial Access Guide Catheter is a sterile, single-use guide catheter.

The SAYA 86 Radial Access Guide Catheter is composed of a guide catheter and a dilator. The guide catheter is a single lumen neurovascular catheter designed for introduction of interventional devices, such as guidewires and other therapeutic devices. The guide catheter consists of three sections: (1) a shaft, (2) a protector and (3) a connector. It is comprised of stainless-steel coils and polymeric materials. The distal portion of the shaft consists of a soft tip and a soft tube. The proximal part of the shaft is covered by the protector and the connector is bonded to the proximal end of the shaft. The shaft is made of Austenitic stainless-steel braids as well as Austenitic stainless-steel coils for durability and resistance to kinking.

A hydrophilic coating is applied to the distal segment of the guide catheter. The inner lumen of the shaft consists of a hydrophobic (PTFE) tube. The guide catheter has a 1mm radiopaque marker on the distal part to aid in visualization.

The SAYA 86 Radial Access Guide Catheter is provided sterile, by ethylene oxide sterilization, and is intended for single use only by physicians who have been adequately trained in neurointerventional procedures.

Comparison with Predicate/Reference Devices

The SAYA 86 Radial Access Guide Catheter has the same intended use and operating principles, and similar technological characteristics compared to the predicate device. While differences exist between the SAYA 86 Radial Access Guide Catheter and predicate device, with respect to the effective length, dimensions, tip shape and materials, those differences do not raise different or new questions of safety and effectiveness.

Device	**Subject Device** SAYA 86 Radial Access Guide Catheter	**Predicate Device** Rist™ 079 Radial Access Guide Catheter	**Reference Device** FUBUKI XF Neurovascular Long Sheath
510(k) Number	K254178	K241388	K213589
Manufacturer	ASAHI INTECC CO., LTD.	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular	ASAHI INTECC CO., LTD.
Regulation Number	21 CFR 870.1250	21 CFR 870.1250	21 CFR 870.1250
Regulation Name	Percutaneous Catheter	Percutaneous Catheter	Percutaneous Catheter
Regulatory Class	II	II	II
Product Code	QJP	QJP, DQY	QJP, DQY
Indications for Use	The SAYA 86 Radial Access Guide Catheter is indicated for the introduction of interventional devices into the neurovasculature.	The Rist™ 079 Radial Access Guide Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	This product is intended to be used to guide interventional devices for neurovascular therapy to a lesion or a procedural site for a percutaneous intravascular procedure in the neurovasculature. This product is also intended to be used for injection of contrast media. This product is intended for use only in the neurovasculature.

Device	**Subject Device** SAYA 86 Radial Access Guide Catheter	**Predicate Device** Rist™ 079 Radial Access Guide Catheter	**Reference Device** FUBUKI XF Neurovascular Long Sheath
Guide Catheter			
Effective Length	80cm, 90cm, 95cm, 100cm,105cm,110cm	95cm, 100cm, 105cm	80cm, 90cm, 100cm, 110cm
Tip Shape	Straight, Angle	Straight	Straight, Angle
Outer Diameter	2.46mm (0.097”, 7Fr)	2.37mm (0.093”, 7Fr)	2.70mm (0.106”, 8Fr)
Inner Diameter	2.19mm (0.086”)	2.00mm (0.079”)	2.28mm (0.090”)
Lubricious Coating/Length	Hydrophilic 20cm	Hydrophilic 25cm	Hydrophilic 8cm
Dilator			
Effective Length	94.5cm, 104.5cm, 109.5cm, 114.5cm, 119.5cm, 124.5cm	Not available	1020mm, 1120mm, 1220mm
Outer Diameter	2.15mm (0.085”)	Not available	2.24mm (0.088”)
Inner Diameter	Distal: 0.91mm (0.036”) Proximal: 1.10mm (0.043”)	Not available	Distal: 0.91mm (0.036”) Proximal: 1.10mm (0.043”)
Other Information			
Accessories	None	Hemostasis Valve	Rotating Hemostasis Valve
Sterilization	Ethylene oxide	Ethylene oxide	Ethylene oxide
Shelf Life	3 years	3 years	3 years
Number of Uses	Single Use	Single Use	Single Use

Non-Clinical Performance Testing

The following performance testing for the SAYA 86 Radial Access Guide Catheter was conducted to support the substantial equivalence determination. The SAYA 86 Radial Access Guide Catheter met all acceptance criteria and performed similarly to the predicate and/or reference devices.

Testing was performed per FDA guidance "*Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters - Premarket Notification (510(k)) Submissions*" and the recommendations provided in ISO 10555-1 "*Intravascular Catheters – Sterile and Single-Use Intravascular Catheters – Part 1: General Requirements*".

Guide Catheter		
Test	Test Method Summary	Results/Conclusion
Dimensional Verification	The device dimensions were measured to confirm they meet design requirements.	All samples met the acceptance criteria.
Simulated Use	The device was used in simulated anatomical model to assess overall performance.	All samples met the acceptance criteria.
Tensile Strength (Catheter Bond Strength)	Tensile force was applied to joints to assess mechanical strength.	All samples met the acceptance criteria.
Tip Pull	Tensile force was applied to tip joint to assess mechanical strength.	All samples met the acceptance criteria.
Tip Flexibility	Stiffness of the device tip was assessed.	All samples met the acceptance criteria.
Kink Resistance	The device was bent to assess resistance to kinking.	All samples met the acceptance criteria.
Torque Strength	The device was rotated in simulated anatomical mode to assess torque durability.	All samples met the acceptance criteria.
Radiopacity	The device was evaluated for visibility under X-ray imaging.	All samples met the acceptance criteria.
Coating Integrity/Particulate Evaluation	The device was tracked in a simulated anatomical model to evaluate coating integrity and particulate generation.	The results were comparable to a similar cleared device.
Lubricity	The lubricity of the coating was assessed.	The results were comparable to a similar cleared device.
Catheter Body Burst Pressure	The device was pressurized until failure to assess burst strength.	All samples met the acceptance criteria.

Guide Catheter		
Test	Test Method Summary	Results/Conclusion
Infusion Flow Rate	The flow rate through the device was measured.	All samples met the acceptance criteria.
Leak (Liquid)	The device was pressurized with liquid and examined for leaks.	All samples met the acceptance criteria.
Leak (Air)	The hub was aspirated and examined for air ingress.	All samples met the acceptance criteria.
Power Injection Burst Pressure	The device was tested for performance during high-pressure injection.	All samples met the acceptance criteria.
Hub Compatibility	The connector was tested per ISO 80369.	All samples met the acceptance criteria.
Surface/Distal Tip	The device surface and tip were examined for cleanliness and absence of defects.	All samples met the acceptance criteria.
Corrosion Resistance	The device was visually examined for any sign of corrosion after immersion into an aqueous solution of sodium chloride to evaluate for occurrence of corrosion.	All samples met the acceptance criteria.
Dilator		
Test	Test Method Summary	Results/Conclusion
Dimensional Verification	The device dimensions were measured to confirm they meet design requirements.	All samples met the acceptance criteria.
Tensile Strength	Tensile force was applied to joints to assess mechanical strength.	All samples met the acceptance criteria.
Radiopacity	The device was evaluated for visibility under X-ray imaging.	All samples met the acceptance criteria.
Surface	The device surface was examined for cleanliness and absence of defects.	All samples met the acceptance criteria.
Distal Tip	The device tip was examined for appearance.	All samples met the acceptance criteria.

Biocompatibility

The guide catheter of the SAYA 86 Radial Access Guide Catheter was tested for the following items per ISO 10993 series and FDA guidance, "*Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*"". All testing performed met the requirements as specified within the applicable standard. The biocompatibility of the dilator was supported by the biocompatibility testing results of the reference device.

Test	Test Method Summary	Results/Conclusion
Cytotoxicity L929 MEM Elution Test	Determine the potential cytotoxicity of a mammalian cell culture (L929) in response to the test article extract.	Non-cytotoxic
Sensitization Kligman Maximization Test	Allergenic or sensitizing potential of the device was evaluated using polar and non-polar extracts in a guinea pig maximization test.	Non-sensitizing
Irritation or Intracutaneous Reactivity Intracutaneous Injection Test	Potential irritation effect of the extract of the device as a result of intracutaneous injection of polar and non-polar extracts was tested.	Non-irritant
Acute Systemic Toxicity Systemic Injection Test	Determine the potential toxic effects of the test article extract as a result of a single-dose systemic injection of polar and non-polar extracts in mice.	Non-toxic
Material Mediated Pyrogenicity Rabbit Pyrogen Test	Determine the potential presence of material-mediated pyrogen.	Non-pyrogenic
Hemocompatibility Rabbit Blood Hemolysis Test	Determine the potential hemolytic activity, via the induction of increased levels of free plasma hemoglobin in rabbit blood, in response to the test article (direct) and its extract (indirect).	Non-hemolytic
Hemocompatibility SC5b-9 Complement Activation Test (Direct Contact)	Human plasma was exposed to the device (direct contact) to determine the potential activation of the SC5b-9 complement system.	Non-activator
Hemocompatibility Partial Thromboplastin Time Test (PTT) (Direct Contact)	Human plasma was exposed to the device (direct contact) to assess any effect on the intrinsic coagulation pathway by measuring clotting time.	Non-activator
Hemocompatibility Platelet and Leukocyte Count Test (PLC) (Direct Contact)	Compared and evaluated the thrombogenicity properties of direct blood contacting components of the SAYA 86 Radial Access Guide Catheter and predicate device *in vitro.*	Test article was not considered to have an effect on platelet and leukocyte concentrations.
Comparative Surface Assessment	Observation at 50x magnification and scanning electron microscopy.	Test article was similar to the predicate device.

Sterilization and Shelf Life

The SAYA 86 Radial Access Guide Catheter is sterilized using ethylene oxide. The sterilization cycle was verified to ensure a sterility assurance level (SAL) of 10^{-6} in accordance with ISO 11135:2014, *"Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation, and routine control of a sterilization process for medical devices".* The packaging integrity and performance testing confirmed that the SAYA 86 Radial Access Guide Catheter remains functional throughout its shelf-life.

Conclusion

The SAYA 86 Radial Access Guide Catheter and the predicate device share the same intended use, operating principles, and similar technological characteristics. Differences in technological characteristics between the SAYA 86 Radial Access Guide Catheter and predicate device do not raise new or different questions of safety and effectiveness. Performance data demonstrate that the device functions as intended. Therefore, the SAYA 86 Radial Access Guide Catheter is substantially equivalent to the predicate device.