June 20, 2025

ASAHI INTECC Co., Ltd.
℅ Esther Kim
Quality System and Regulatory Affairs Associate
ASAHI INTECC USA, Inc.
3002 Dow Avenue, Suite 212
Tustin, California 92780

Re: K251560
Trade/Device Name: FUBUKI XF-R Neurovascular Long Sheath
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP
Dated: May 21, 2025
Received: May 21, 2025

Dear Esther Kim:

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.

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, Ph.D.
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)*
K251560

Device Name
FUBUKI XF-R Neurovascular Long Sheath

Indications for Use *(Describe)*
The FUBUKI XF-R Neurovascular Long Sheath 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. The FUBUKI XF-R Neurovascular Long Sheath is also intended to be used for injection of contrast media.
The FUBUKI XF-R Neurovascular Long Sheath is intended for use only in 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.

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)

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FUBUKI XF-R Neurovascular Long Sheath

510(k) K251560

Date Prepared:	21 MAY, 2025
Applicant:	ASAHI INTECC CO., LTD. 3-100 Akatsuki-cho, Seto, Aichi 489-0071 Japan
Contact:	Esther Kim Quality System and Regulatory Affairs Associate ASAHI INTECC USA, Inc. 3002 Dow Avenue, Suite 212 Tustin, CA 92780 Office: (949) 756-8901 ext. 508 e-mail: aiu_ra@asahi-intecc-us.com
Device Name:	FUBUKI XF-R Neurovascular Long Sheath
Device Classification:	Class II, 21 CFR § 870.1250
Regulation Name:	Percutaneous Catheter
Product Code:	QJP – Catheter, Percutaneous, Neurovasculature
Predicate Device:	FUBUKI XF Neurovascular Long Sheath (K213589)

Intended Use/Indications For Use

The FUBUKI XF-R Neurovascular Long Sheath 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. The FUBUKI XF-R Neurovascular Long Sheath is also intended to be used for injection of contrast media.
The FUBUKI XF-R Neurovascular Long Sheath is intended for use only in the neurovasculature.

Device Description

The FUBUKI XF-R Neurovascular Long Sheath (FUBUKI XF-R) consists of a long sheath and a dilator. The long sheath is a single lumen neurovascular catheter designed for introduction of interventional devices, such as guidewires and other therapeutic devices. The long sheath consists of three sections: (1) a shaft, (2) a protector and (3) a connector. 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 (strain relief) and the connector is bonded to the proximal end of the shaft.

The subject device is provided sterile, by ethylene oxide, and is intended for single use only by physicians who have been adequately trained in neurointerventional procedures.

The outer surface of the long sheath is coated with a hydrophilic polymer and the inner lumen of the shaft (excluding the connector portion) is lined with a fluoropolymer layer to facilitate movement of the guidewire and other devices.

The dilator consists of two parts: (1) a shaft and (2) a connector.

The FUBUKI XF-R is supplied with a dilator and rotating hemostasis valve (RHV) packed in a sterile package.

Comparison with Predicate Device

The subject FUBUKI XF-R and the predicate FUBUKI XF have the same intended use and the same or similar technological characteristics such as components, design, materials, sterilization method, shelf life and operating principle.

The following technological differences exist between the subject and predicate devices:

- Hydrophilic coating length of the long sheath
- Addition of a 95cm model and exclusion of the 110cm model for the long sheath
- Exclusion of the Angled tip long sheath model
- Addition of a 117cm dilator

These differences do not raise new or different questions of safety and effectiveness. The results of the non-clinical testing provide reasonable assurance of substantial equivalence to the predicate device.

Comparison of Intended Use and Technological Characteristics to Predicate Device

Device Name	Subject Device FUBUKI XF-R Neurovascular Long Sheath	Predicate Device FUBUKI XF Neurovascular Long Sheath
510(k) Number	K251560	K213589
Manufacturer	ASAHI INTECC CO., LTD.	
Regulation Number	21 CFR § 870.1250	
Regulation Name	Catheter, Percutaneous, Neurovasculature	
Regulatory Class	II	
Product Code	QJP	
Intended Use and Indications for Use	The FUBUKI XF-R Neurovascular Long Sheath 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. The FUBUKI XF-R Neurovascular Long Sheath is also intended to be used for injection of contrast media. The FUBUKI XF-R Neurovascular Long Sheath is intended for use only in the neurovasculature.	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.
Long Sheath		
Outer Diameter	2.70mm (0.106”, 8Fr)	
Inner Diameter	2.28mm (0.090”, 6.8Fr)	
Effective Length	80cm, 90cm, 95cm, 100cm	80cm, 90cm, 100cm, 110cm
Tip Shape	Straight	Straight, Angled
Coating	Hydrophilic	
Construction	Soft tip, soft tube and shaft, protector, connector	
Coating Length	20cm	8cm
Inner Lumen	PTFE	
Dilator		
Effective Length	102cm, 112cm, 117cm, 122cm	102cm, 112cm, 122cm
Outer Diameter	2.24mm (0.088”)	
Inner Diameter	0.91mm (0.036”)	
Other Information		

Accessory	Hemostasis Valve (Rotating Hemostasis Valve)
Sterilization Method	Ethylene Oxide Gas
Sterilization Level	SAL 10^{-6}
Shelf Life	3 years
Single Use	Yes

Non-Clinical Bench Testing / Performance Data

The following non-clinical bench testing was performed for the FUBUKI XF-R Neurovascular Long Sheath to support the substantial equivalence determination. The FUBUKI XF-R met all acceptance criteria and performed similarly to the predicate FUBUKI XF. Testing was performed per FDA guidance "*Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters - Premarket Notification (510(k)) Submissions*" and the recommendations in ISO 10555-1 "*Intravascular Catheters – Sterile and Single-Use Catheters – Part 1: General Requirements*".

- Dimensional Verification
- Simulated Use
- Lubricity
- Coating Integrity / Particulate Evaluation
- Appearance

Biocompatibility

The FUBUKI XF-R was tested 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.

Test	Test Method Summary	Conclusions
Cytotoxicity MEM Elution Test	Per ISO 10993-5	Non-Cytotoxic
Sensitization Kligman Maximization Test	Per ISO 10993-10	Non-Sensitizing
Intracutaneous Reactivity Intracutaneous Injection Test	Per ISO 10993-23	Non-Irritant
Acute Systemic Toxicity System Injection Test	Per ISO 10993-11	Non-Toxic
Material Mediated Pyrogenicity Rabbit Pyrogen Test	Per ISO 10993-11	Non-Pyrogenic
Hemocompatibility Rabbit Blood Hemolysis Test (Direct and Indirect Contact)	Per ISO 10993-4	Non-Hemolytic
Hemocompatibility Complement Activation Test (SC5b-9) (Direct Contact)	Per ISO 10993-4	Non-Activator

Hemocompatibility Partial Thromboplastin Time Test (PTT) (Direct Contact)	Per ISO 10993-4	Non-Activator
Thrombogenicity *In Vivo* Thrombogenicity Study	Per ISO 10993-4	Comparable thromboresistance to the predicate device.

Sterilization and Shelf Life

The changes to the subject device do not impact sterilization and shelf life as compared to the predicate device. The shelf-life of the subject device was supported by device performance testing following 3-year accelerated aging.

Conclusion

The FUBUKI XF-R Neurovascular Long Sheath has the same intended use and the same or similar technological characteristics such as components, design, materials, sterilization method, and operating principles as the predicate device. The differences between the subject and predicate device do not raise different or new questions of safety or effectiveness. The non-clinical tests demonstrate that the subject device performs as intended and that the FUBUKI XF-R Neurovascular Long Sheath is substantially equivalent to the predicate FUBUKI XF Neurovascular Long Sheath (K213589).