March 24, 2022

ASAHI INTECC Co., Ltd.
% Cynthia Valenzuela
Director, Regulatory Affairs
ASAHI INTECC USA, Inc.
3002 Dow Avenue, Suite 212
Tustin, California 92780

Re: K213589
Trade/Device Name: FUBUKI XF Neurovascular Long Sheath
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: February 18, 2022
Received: February 22, 2022

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213589

Device Name
FUBUKI XF Neurovascular Long Sheath

Indications for Use *(Describe)*
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.

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)]

510(k) K213589

DATE PREPARED:	21 March 2022
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: (949) 413 0071 Email: cynthiav@asahi-intecc-us.com
SECONDARY CONTACT:	Mr. Hiroshi Obara Manager, Regulatory Affairs ASAHI INTECC CO., LTD. 3-100 Akatsuki-cho Seto, Aichi, Japan 489-0071 Email: hiroshi.obara@asahi-intecc.com
TRADE NAME:	FUBUKI XF Neurovascular Long Sheath
DEVICE CLASSIFICATION:	Class II, 21 CFR §870.1250
CLASSIFICATION NAME:	Percutaneous Catheter
PRODUCT CODE:	QJP – Catheter, Percutaneous, Neurovasculature DQY – Catheter, Percutaneous
PREDICATE DEVICE(S):	ASAHI FUBUKI 043 and ASAHI FUBUKI Guide Catheters (K141981)

Intended Use/Indications for Use:

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 Description:

The FUBUKI XF Neurovascular Long Sheath 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 FUBUKI XF Neurovascular Long Sheath 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 to provide high lubricity when the surface is wet. The inner lumen of the shaft (excluding the connector portion) is lined with a fluoropolymer layer to facilitate movement of the guide wire and other devices.

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

The FUBUKI XF Neurovascular Long Sheath is composed of a long sheath and a dilator packed in a sterile package. This sterile package is packed in an outer box with the Instructions for Use.

Accessories:

The FUBUKI XF Neurovascular Long Sheath is packaged with a rotating hemostasis valve (RHV).

Comparison with Predicate Device:

The FUBUKI XF Neurovascular Long Sheath subject to this submission has the same intended use and similar technological characteristics, such as components, design, materials, sterilization method, shelf life and operating principles as the predicate device.

Comparison with Predicate Device

Name of Device	ASAHI FUBUKI Guide Catheters (8Fr)	FUBUKI XF Neurovascular Long Sheath
	Predicate Device	Subject Device
	K141981	K213589
Regulatory Status		
Regulation Number	21 CFR §870.1250	21 CFR §870.1250
Device Classification Name	Catheter, Percutaneous	Catheter, Percutaneous, Neurovasculature
Regulatory Class	II	II
Product Code	DQY	QJP DQY
Indications for Use	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 catheter is also intended to be used for injection of contrast media. Do not use this product other than for use 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.
Product Information:		
Labeled Shaft Outer Diameter of Long Sheath	2.70mm (8 Fr, 0.106 inch)	2.70mm (8 Fr, 0.106 inch)
Labeled Shaft Inner Diameter of Long Sheath	0.090 inch (6.8Fr, 2.28mm)	0.090 inch (6.8Fr, 2.28mm)
Long Sheath Effective Length	800mm, 900mm, 1000mm, 1100mm	800mm, 900mm, 1000mm, 1100mm
Dilator Effective Length	925mm, 1025mm, 1125mm, 1225mm	1020mm, 1120mm, 1220mm
Dilator Outer Diameter (Proximal)	2.21mm (6.6Fr, 0.087 inch)	2.24mm (6.7Fr, 0.088 inch)
Tip Shape	Straight	Straight, Angled
Long Sheath Distal Coating	Hydrophilic (50mm)	Hydrophilic (80mm)
Construction	Soft tip, soft tube and shaft, protector, connector	Soft tip, soft tube and shaft, protector, connector
Long Sheath Inner Lumen	PTFE	PTFE
Accessories	None	Hemostasis Valve
Sterilization Method	Ethylene Oxide Gas	Ethylene Oxide Gas
Sterilization Level	SAL 10^{-6}	SAL 10^{-6}
Shelf Life	3 years	3 years
Single Use	Yes	Yes

NON-CLINICAL TESTING / PERFORMANCE DATA:

The following non-clinical bench testing was performed on the FUBUKI XF Neurovascular Long Sheath (long sheath and dilator) to determine substantial equivalence:

Long Sheath

Test	Result
Visual Inspection	Pass
Air Leakage	Pass
Burst Pressure Under Static Condition	Pass
Corrosion Resistance	Pass
Dimensional Verification	Pass
Kink Resistance	Pass
Liquid Leakage	Pass
Radio-Detectability	Pass
Slidability	Pass
Tensile Strength	Pass
Tensile Strength (Distal Tip)	Pass
Coating Integrity / Particulate Evaluation	(Characterization Only)
Simulated Use Test	Pass
Flowrate	Pass
Power Injection Test	Pass
Tip Flexibility	Pass
Torque Strength	Pass

Dilator

Test	Result
Visual Inspection	Pass
Corrosion Resistance	Pass
Dimensional Verification	Pass
Radio-Detectability	Pass
Tensile Strength	Pass

The bench tests performed on finished sterilized product demonstrated that the FUBUKI XF Neurovascular Long Sheath is substantially equivalent to the cleared predicate K141981. No new questions of safety and effectiveness were identified with the design change. The acceptance criteria were based on ISO standards identified, as applicable, and were identical to the acceptance criteria used for the predicate ASAHI FUBUKI Guide Catheters (K141981).

BIOCOMPATIBILITY:

Biocompatibility testing was performed in accordance to ISO 10993. All testing performed met the requirements as specified within the applicable standard.

Per ISO 10993-1, the FUBUKI XF Neurovascular Long Sheath was categorized as an externally communicating device with circulating blood contact for a limited duration (<24 hours).

Biocompatibility Test Results for Long Sheath

Test	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-Toxic
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 article sites should not show a significantly greater biological reaction than the sites injected with the control article.	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
Hemocompatibility Rabbit Blood Hemolysis Test	ISO 10993-4 No deviations	The test article in direct contact with blood and test article extract must be non-hemolytic.	Non-Hemolytic
Material Mediated Pyrogenicity Rabbit Pyrogen Test	ISO10993-11 No deviations	The test article should not increase the temperature of any of the animals by more than 0.5 degrees Celsius.	Non-Pyrogenic
Hemocompatibility Unactivated Partial Thromboplastin Time Test	ISO 10993-4 No deviations	The UPTT of the plasma exposed to test article extract should not be significantly decreased when compared the UPTT of the plasma exposed to the negative control or the untreated control.	Not an 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
Thrombogenicity 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.	Comparable thromboresistance with control

Biocompatibility Test Results for Dilator

Test	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-Toxic
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 article sites should not show a significantly greater biological reaction than the sites injected with the control article.	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
Hemocompatibility Rabbit Blood Hemolysis Test	ISO 10993-4 No deviations	The test article in direct contact with blood and test article extract must be non-hemolytic.	Non-Hemolytic
Material Mediated Pyrogenicity Rabbit Pyrogen Test	ISO10993-11 No deviations	The test article should not increase the temperature of any of the animals by more than 0.5 degrees Celsius.	Non-Pyrogenic
Hemocompatibility Unactivated Partial Thromboplastin Time Test	ISO 10993-4 No deviations	The UPTT of the plasma exposed to test article extract should not be significantly decreased when compared the UPTT of the plasma exposed to the negative control or the untreated control.	Not an 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
Thrombogenicity 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.	Comparable thromboresistance with control

STERILIZATION and SHELF LIFE:

The FUBUKI XF Neurovascular Long Sheath sterilization process using Ethylene Oxide (EO) has been validated in accordance with ISO 11135-1:2014 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 2.15 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 FUBUKI XF Neurovascular Long Sheath has similar intended use and similar technological characteristics, such as components, design, materials, sterilization method, shelf life and operating principles, as the predicate device ASAHI FUBUKI Guide Catheters. Performance data demonstrate that the device functions as intended. Therefore, the FUBUKI XF Neurovascular Long Sheath is considered substantially equivalent to the predicate device.