December 10, 2021

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

Re: K203723
Trade/Device Name: Branchor Balloon Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: November 4, 2021
Received: November 8, 2021

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)*
K203723

Device Name
Branchor Balloon Guide Catheter

Indications for Use *(Describe)*

The Branchor Balloon Guide Catheter is indicated for use to facilitate the insertion and guidance of an intravascular catheter into a selected blood vessel in the neuro vasculature, and injection of contrast media.

The balloon provides temporary vascular occlusion during these procedures.

The Branchor Balloon Guide Catheter can also be used as a conduit for retrieval devices.

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.

510(K) Summary
[as required by 21 CFR §807.92(c)]

510(K) K203723

DATE PREPARED:	10 December 2021
SUBMITTER:	ASAHI INTECC CO., LTD 3-100 Akatsuki-cho, Seto Aichi 489-0071, Japan Telephone: +81 561 48 5551
PRIMARY CONTACT:	Mrs. Cynthia Valenzuela Director, Global Regulatory Affairs ASAHI INTECC USA, INC. 3002 Dow Avenue, Suite 212 Tustin, California 92780 Phone: (714) 442 0575 Email: cynthiav@asahi-intecc-us.com
TRADE NAME:	Branchor Balloon Guide Catheter
DEVICE CLASSIFICATION:	Class II, 21 CFR §870.1250
CLASSIFICATION NAME:	Percutaneous Catheter
PRODUCT CODE:	QJP, Catheter, Percutaneous, Neurovasculature DQY, Catheter, Percutaneous
PREDICATE DEVICE:	**Primary Predicate Device:** CELLO Balloon Guide Catheter (K120781; August 9, 2012) **Reference Predicate Device:** 8F FlowGate Balloon Guide Catheter (K153729; January 27, 2016)

Device Description:

This balloon guide catheter is a variable stiffness catheter that has a radio-opaque marker at the distal end of the balloon and a branched connector at the proximal end, and is equipped with a braid reinforced coaxial lumen. A balloon is attached to the distal end, and the dimensions of this balloon guide catheter and the recommended balloon injection volume are indicated on the product label. The balloon guide catheter is provided sterile, using ethylene oxide, and is intended for single use only by physicians who have been adequately trained in neurointerventional procedures.

The outer surface of this balloon guide catheter is coated with a hydrophilic coating in order to enhance lubricity when the surface is wet. The shaft lumen is provided with PTFE coating, except the connector part, to facilitate the passage of the guidewire and other devices through the section.

Accessories

The Branchor Balloon Guide Catheter is packaged with a peel-away to protect the balloon during catheter introduction, a syringe for balloon inflation and deflation, and a three-way stopcock to connect the syringe for inflation and deflation of the balloon.

Intended Use/Indications for Use

The Branchor Balloon Guide Catheter is indicated for use to facilitate the insertion and guidance of an intravascular catheter into a selected blood vessel in the neuro vasculature, and injection of contrast media.

The balloon provides temporary vascular occlusion during these procedures.

The Branchor Balloon Guide Catheter can also be used as a conduit for retrieval devices.

Comparison of Technological Characteristics:

The Branchor Balloon Guide Catheter has similar

- Indications for use,
- Fundamental scientific technology,
- Fundamental design,
- Packaging and sterilization of devices

as the marketed predicate devices. A tabular comparison of the specific technological characteristics between the predicate devices and the subject device is provided below. The technological differences do not raise new questions of safety and effectiveness.

Table 1: Comparison Table

Name of Device	CELLO Balloon Guide Catheter	8F FlowGate Balloon Guide Catheter	Branchor Balloon Guide Catheter
510(K) Number:	K120781	K153729	SUBJECT DEVICE K203723
Intended Use and Indications	The CELLO Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of intravascular catheters into a selected blood vessel in the peripheral and neuro vasculature systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures.	FlowGate Balloon Guide Catheters are indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for Retrieval devices.	The Branchor Balloon Guide Catheter is indicated for use to facilitate the insertion and guidance of an intravascular catheter into a selected blood vessel in the neuro vasculature, and injection of contrast media. The balloon provides temporary vascular occlusion during these procedures. The Branchor Balloon Guide Catheter can also be used as a conduit for retrieval devices.
Device Description	The CELLO Balloon Guide Catheter is a coaxial-lumen, braid-reinforced, variable stiffness catheter with two radiopaque markets on both the distal and proximal ends of the balloon and a bifurcated luer hub on the proximal end. A compliant silicone balloon is mounted on the distal end. Balloon Guide Catheter dimensions and the recommended balloon inflation volumes are indicated on product label.	The FlowGate Balloon Guide Catheter are coaxial-lumen, braid- reinforced, variable stiffness catheters designed for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. A radiopaque market is included on the distal end for angiographic visualization. A compliant balloon is mounted on the distal end to provide temporary vascular occlusion during angiographic procedures. A bifurcated luer hub on the proximal end allows attachments for flushing, inflation and aspiration. Balloon Guide Catheter dimensions and maximum recommended balloon inflation volume are indicated on product label.	This balloon guide catheter is a variable stiffness catheter that has a radio-opaque marker at the distal end of the balloon to facilitate fluoroscopic visualization and indicate the balloon position, a branched connector at the proximal end, and is equipped with a braid reinforced coaxial lumen. A balloon is attached to the distal end, and the dimensions of this balloon guide catheter and recommended balloon injection volume are provided on the product label. The outer surface of this balloon guide catheter is coated with a hydrophilic coating for enhanced lubricity when the surface is wet.

Name of Device	CELLO Balloon Guide Catheter	8F FlowGate Balloon Guide Catheter	Branchor Balloon Guide Catheter
			The shaft lumen is provided with PTFE coating, with the exception of the connector section to facilitate the passage of the guidewire and other devices through the section.
Regulatory Status:			
Regulation Number:	21 CFR § 870.1250	21 CFR § 870.1250	21 CFR § 870.1250
Regulation Description:	Percutaneous Catheter	Percutaneous Catheter	Catheter, Percutaneous, Neurovasculature
Regulatory Class:	II	II	II
Product Code:	DQY	DQY	QJP DQY
Product Information:			
Size	6F, 7F, 8F, 9F	Shaft OD: 8F; Shaft ID: 6.4F	Shaft OD: 9F; Shaft ID: 6.84F
Effective Length	92cm to 102cm	95cm and 85cm	90cm, 100cm
Balloon Material	Silicone Rubber	Silicone Elastomer	Polyurethane Elastomer
Shaft Material	Polyurethane Polyamide Stainless Steel PFA	Pebax Polyamide Stainless Steel PTFE	Polyurethane Elastomer Polyamide 12 Elastomer Polyamide 12 Stainless Steel Polytetrafluoroethylene
Accessories	Unknown	Dilator Peel-away Sheath Rotating Hemostatic Valve Tuohy Borst Valve with Sideport Lure-Activated Valve	Peel-away Syringe Three-way Stopcock
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Sterility Level	$SAL10^{-6}$	$SAL10^{-6}$	$SAL10^{-6}$
Single Use	Yes	Yes	Yes
Radiopaque Markers	Yes	Yes	Yes
Anatomical Sites	Peripheral and neuro vascular	Peripheral and neuro vascular	Neuro vascular

NON-CLINICAL TESTING / PERFORMANCE DATA:

Non-clinical bench testing was performed on the Branchor Balloon Guide Catheter to determine substantial equivalence. The following testing was performed:

Table 2: Performance Testing

Test	Result
Air Leakage Into Hub Assembly During Aspiration	Pass
Balloon Diameter to Inflation Pressure	Pass
Balloon Inflation and Deflation Times	Pass
Balloon Maximum Diameter	Pass
Burst Pressure	Pass
Coating Integrity/Particulate Evaluation	(Characterization Only)
Design Verification – Simulated Use	Pass
Dimensional Analysis	Pass
Freedom from Leakage and Damage on Inflation	Pass
Kink Resistance Test	Pass
Liquid Leakage Under Pressure	Pass
Lumen Collapse Under Maximum Aspiration	Pass
Luer Hub Testing	Pass
Peak Tensile Strength - Tip	Pass
Peak Tensile Strength - Tube Junction	Pass
Radio-detectability	Pass
Tip Flexibility	Pass
Torque Strength	Pass
Visual Inspection - Distal Tip	Pass
Visual Inspection - Surface	Pass

The *in vitro* bench tests demonstrated that the Branchor Balloon Guide Catheter met all acceptance criteria and performed similarly to the predicate devices. Performance data demonstrates that the device functions as intended and has a safety and effectiveness profile that is similar to the predicate devices.

BIOCOMPATIBILITY:

The Branchor Balloon Guide Catheter was tested in accordance with ISO 10993-1, and found to be biocompatible. The following tests were performed:

Table 2: Biocompatibility Results

Test	Test Summary	Conclusion
Systemic Toxicity - ISO 10993-11 Rabbit Pyrogen Test (material mediated)	The test article should not increase the rectal temperature of any of the animals by more than 0.5 °C.	Non-pyrogenic
Systemic Toxicity - ISO 10993-11 Systemic Injection	The test article must not show significantly greater biological activity than the control.	No acute systemic toxicity
Cytotoxicity - ISO 10993-5 L929 cells/MEM Elution Test	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 - ISO 10993-10 Guinea Pig Maximization Test	The extracts should show no evidence of causing delayed dermal contact sensitization in the guinea pig.	Non-sensitizing
Irritation - ISO 10993-10 Intracutaneous Injection Test	The test extract and the negative control must exhibit similar edema and erythema scores.	Non-irritant
Hemocompatibility - ISO 10993-4 Hemolysis	Test article in direct contact with blood and test article extract must be non-hemolytic.	Non-hemolytic
Hemocompatibility - ISO 10993-4 Partial Thromboplastin Time Assay (PTT)	The PTT of the plasma exposed to test article extract should not significantly decreased when compared to untreated and negative controls.	Minimal Activator
Hemocompatibility - ISO 10993-4 Complement Activation Assay (SC5b-9)	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.	Non-Potential Activator
Hemocompatibility – ISO 10993-4 Thrombogenicity	Compare results of test article to predicate control Thrombogenicity response in NAVI model. Determine acceptability of results as part of risk management.	No Thrombosis

STERILIZATION and SHELF LIFE:

The Branchor Balloon Guide Catheter 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 Branchor Balloon Guide Catheter has similar intended use, similar technological characteristics, such as components, design, materials, sterilization method, shelf life and operating principles, as the predicate devices. Performance data demonstrate that the device functions as intended. The conclusions drawn from the nonclinical tests demonstrate that the Branchor Balloon Guide Catheter is substantially equivalent to the legally marketed predicate devices.