October 11, 2022

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

Re: K221951
Trade/Device Name: Branchor Balloon Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP
Dated: September 7, 2022
Received: September 13, 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)*
K221951

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.

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

510(K) K221951

DATE PREPARED:	11 OCT 2022
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: (949) 413 0071 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
PREDICATE DEVICE:	Branchor Balloon Guide Catheter (K203723)

Device Description:

The Branchor Balloon Guide Catheter has the same design, materials and accessories as the predicate device (K203723). The change to the subject device includes performance testing and labeling to allow use with a power injector.

This balloon guide catheter is a variable stiffness catheter that has a radiopaque 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 1mL 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 Indications for Use and Technological Characteristics:

The Branchor Balloon Guide Catheter has identical

- Indications for use,
- Fundamental principles of operation,
- Fundamental design and materials,
- Packaging and sterilization of devices

as the marketed predicate device. A tabular comparison of the specific technological characteristics between the predicate device and subject device is provided below. The labeling changes to allow the use of power injectors with the subject device do not raise new questions of safety and effectiveness.

Table 1: Comparison Table

Name of Device	Branchor Balloon Guide Catheter	Branchor Balloon Guide Catheter
	Predicate	Subject Device
510(K) Number:	K203723	K221951
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.	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	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. 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.	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. 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.

Name of Device	Branchor Balloon Guide Catheter	Branchor Balloon Guide Catheter
510(K) Number:	K203723	K221951
Regulation Number:	21 CFR § 870.1250	21 CFR § 870.1250
Regulation Description:	Catheter, Percutaneous, Neurovasculature	Catheter, Percutaneous, Neurovasculature
Regulatory Class:	II	II
Product Code:	QJP DQY	QJP
Product Information:		
Size	Shaft OD: 3.00 mm Shaft ID: 2.28 mm	Shaft OD: 3.00 mm Shaft ID: 2.28 mm
Effective Length	90 cm, 100 cm	90 cm, 100 cm
Balloon Material	Polyurethane elastomer	Polyurethane elastomer
Shaft Material	Polyurethane Elastomer Polyamide 12 Elastomer Polyamide 12 Stainless Steel Polytetrafluoroethylene	Polyurethane Elastomer Polyamide 12 Elastomer Polyamide 12 Stainless Steel Polytetrafluoroethylene
Accessories	Peel-away Syringe Three way stopcock	Peel-away Syringe Three way stopcock
Sterilization Method	Ethylene Oxide	Ethylene Oxide
Sterility Level	$SAL10^{-6}$	$SAL10^{-6}$
Single Use	Yes	Yes
Radiopaque Markers	Yes	Yes
Anatomical Sites	Neuro vascular	Neuro vascular

PERFORMANCE TESTING:

Non-clinical bench testing was performed on the Branchor Balloon Guide Catheter to allow use with power injectors. The following testing was performed:

Table 2: Performance Testing

Test	Result
Burst Pressure under static condition	Pass
Power Injection	Pass
Flow Rate	Pass

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

BIOCOMPATIBILITY, STERILIZATION and SHELF LIFE:

The change to the subject device does not impact biocompatibility, sterilization, and shelf life, as compared to the predicate device.

CONCLUSION:

The Branchor Balloon Guide Catheter has similar intended use, same technological characteristics, such as components, design, materials, sterilization method, shelf life and operating principles, as the predicate device. Performance data demonstrate that the subject 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 device.