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: K251240
Trade/Device Name: Branchor X Balloon Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP
Dated: April 21, 2025
Received: April 22, 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
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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)*
K251240

Device Name
Branchor X Balloon Guide Catheter

Indications for Use *(Describe)*
The Branchor X 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 X 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.

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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Branchor X Balloon Guide Catheter

K251240

Date Prepared:	11 June 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

Trade/Device Name:	Branchor X Balloon Guide Catheter
Regulation Number:	21 CFR § 870.1250
Classification Name:	Percutaneous Catheter
Device Classification:	Class II
Product Code:	QJP – Catheter, Percutaneous, Neurovasculature

Predicate Device:	Branchor Balloon Guide Catheter (K221951)
Reference Devices:	Branchor Balloon Guide Catheter (K203723) CELLO Balloon Guide Catheter (K120781)

I. DEVICE DESCRIPTION

The Branchor X Balloon Guide Catheter is a variable stiffness catheter that has a radiopaque 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 lumen. A balloon is attached to the distal end, and the dimensions of the 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. This allows the guidewire and other devices to easily move through the section.

The Branchor X Balloon Guide Catheter is packaged with a luer-activated valve, a syringe, a three-way stopcock, a rotating hemostasis valve (RHV), and a peel-away accessories.

II. INDICATIONS FOR USE

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

III. COMPARISON OF INDICATIONS FOR USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE

The comparison of the Branchor X Balloon Guide Catheter and the predicate Branchor Balloon Guide Catheter (K221951) shows that the devices have the same intended use and same or similar technological characteristics, such as components, design, materials, sterilization method, and operating principle. The technological differences do not raise new questions of safety and effectiveness.

A tabular comparison of the intended use and specific technological characteristics between the subject, predicate and reference devices is provided below:

Name of Devices	Branchor X Balloon Guide Catheter (subject)	Branchor Balloon Guide Catheter (predicate)	Branchor Balloon Guide Catheter (reference)	CELLO Balloon Guide Catheter (reference)
510(k)	K251240	K221951	K203723	K120781
Indications for Use	The Branchor X 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 X 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.	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 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.

Device Description	This balloon guide catheter is a variable stiffness catheter that has a radiopaque 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 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 radiopaque 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 radiopaque 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 passag of the guidewire and other devices through the section.	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.
Regulation Number	21 CFR § 870.1250	21 CFR § 870.1250	21 CFR § 870.1250	21 CFR § 870.1250
Regulation Description	Catheter, Percutaneous, Neurovasculature	Catheter, Percutaneous, Neurovasculature	Catheter, Percutaneous, Neurovasculature	Percutaneous Catheter

Regulatory Class	II	II	II	II
Product Code	QJP	QJP	QJP, DQY	DQY
Size	Shaft OD: 2.70 mm, 3.00 mm Shaft ID: 2.19 mm, 2.42 mm	Shaft OD: 3.00 mm Shaft ID: 2.28 mm	Shaft OD: 3.00 mm Shaft ID: 2.28 mm	6 Fr, 7 Fr, 8 Fr, 9 Fr
Effective Length	90 cm, 95 cm, 97 cm	90 cm, 100 cm	90 cm, 100 cm	92 cm to 102 cm
Balloon Material	Polyurethane elastomer	Polyurethane elastomer	Polyurethane elastomer	Silicone rubber
Shaft Materials	Polyurethane Elastomer Polyamide 12 elastomer Polyamide 12 Stainless steel Tungsten Polytetrafluoroethylene	Polyurethane Elastomer Polyamide 12 elastomer Polyamide 12 Stainless steel Polytetrafluoroethylene	Polyurethane Elastomer Polyamide 12 elastomer Polyamide 12 Stainless steel Polytetrafluoroethylene	Polyurethane Polyamide Stainless steel PFA
Accessories	Luer-activated valve RHV Peel-away Syringe Three-way stopcock	Peel-away Syringe Three-way stopcock	Peel-away Syringe Three-way stopcock	Dilator
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Sterility Level	$SAL10^{-6}$	$SAL10^{-6}$	$SAL10^{-6}$	$SAL10^{-6}$
Shelf Life	0.5 years	3 years	3 years	Unknown
Single Use	Yes	Yes	Yes	Yes
Radiopaque Markers	Yes	Yes	Yes	Yes
Anatomical Sites	Neurovascular	Neurovascular	Neurovascular	Peripheral and neurovascular

IV. TESTING SUMMARY

Non-Clinical Testing / Performance Data
Non-clinical bench testing was performed on the Branchor X Balloon Guide Catheter to determine substantial equivalence. The following testing/assessments were performed:

Test	Test Method Summary	Results/Conclusion
Dimensional Verification	The device dimensions were measured to confirm they meet design specifications.	All samples met the acceptance criteria.
Distal Tip Visual Inspection	The distal tip was visually inspected for appropriate shape and smoothness.	All samples met the acceptance criteria.
Surface Visual Inspection	The catheter surface was checked for cleanliness and absence of defects.	All samples met the acceptance criteria.
Radio-Detectability	The device was evaluated for visibility under X-ray imaging.	All samples met the acceptance criteria.
Balloon Diameter to Inflation Pressure	The balloon was inflated and its diameter was measured at various inflation levels.	All samples met the acceptance criteria.
Freedom from Leakage and Damage on Inflation	The balloon was repeatedly inflated and deflated to check for leakage or damage.	All samples met the acceptance criteria.
Balloon Maximum Diameter	The balloon was inflated to its maximum volume and checked for integrity.	All samples met the acceptance criteria.
Liquid Leakage under Pressure	The catheter was pressurized with liquid and checked for leaks.	All samples met the acceptance criteria.
Air Leakage into Hub Assembly during Aspiration	The hub was aspirated and checked for air ingress.	All samples met the acceptance criteria.
Peak Tensile Strength	Tensile force was applied to joints to assess mechanical strength.	All samples met the acceptance criteria.
Kink Resistance	The catheter was bent to assess resistance to kinking.	All samples met the acceptance criteria.
Tip Flexibility	The flexibility of the distal tip was measured.	All samples met the acceptance criteria.
Flow Rate	The flow rate through the catheter was measured.	All samples met the acceptance criteria.
Burst Pressure under Static Condition	The device was pressurized until failure to assess burst strength.	All samples met the acceptance criteria.
Power Injection	The device was tested for performance during high-pressure injection.	All samples met the acceptance criteria.
Torque Strength	The device was rotated to assess resistance to torsional stress.	All samples met the acceptance criteria.
Coating Integrity/Particulate	The device was tracked in a simulated anatomical model to evaluate coating integrity and particulate release.	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.
Connector	The connector was tested for leakage, mechanical integrity, and compatibility.	All samples met the acceptance criteria.

Non-clinical bench testing demonstrated that the Branchor X Balloon Guide Catheter met all pre-established acceptance criteria, functions as intended, and has a safety and effectiveness profile that is similar to the predicate device and the reference devices.

Biocompatibility Testing

The biocompatibility evaluation for the Branchor X Balloon Guide Catheter was conducted in accordance with the FDA guidance, "Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process"," and International Standard ISO 10993 series. The biocompatibility testing included the following tests:

Test	Test Summary	Conclusion
Cytotoxicity MEM Elution Test ISO 10993-5	Determine the potential cytotoxicity of a mammalian cell culture (L929) in response to the test article extract.	Non-cytotoxic
Sensitization Maximization Test ISO 10993-10	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 ISO 10993-23	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 ISO 10993-11	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 ISO 10993-11	Determine the potential presence of material-mediated pyrogen.	Non-pyrogenic
Hemocompatibility Hemolysis ISO 10993-4	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 Complement Activation (SC5b-9) ISO 10993-4	Human plasma was exposed to the device (direct contact) to determine the potential activation of the SC5b-9 complement system.	Non-activator
Hemocompatibility Unactivated Partial Thromboplastin Time Assay (UPTT) ISO 10993-4	Human plasma was exposed to the device (direct contact) to assess any effect on the intrinsic coagulation pathway by measuring clotting time (UPTT).	Non-activator
Hemocompatibility Thrombogenicity ISO 10993-4	Compared the thrombogenicity properties of direct blood contacting components of the subject and commercially available control devices *in vivo.*	Comparable thromboresistance to commercially available comparator devices

Per ISO 10993-1, the Branchor X Balloon Guide Catheter was categorized as an externally communicating device with circulating blood contact for a limited duration of contact (≤ 24 hours).

Sterilization and Shelf Life
The Branchor X 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 6 months shelf-life.

Animal Study
Animal study was not deemed necessary to demonstrate substantial equivalence.

Clinical Study
Clinical study was not deemed necessary to demonstrate substantial equivalence.

V. CONCLUSIONS

The Branchor X Balloon Guide Catheter has the same intended use and similar technological characteristics such as components, design, materials, sterilization method, and operating principles as the predicate device. Performance testing demonstrates that the device functions as intended. The differences between the subject and predicate device do not raise different or new questions of safety or effectiveness. The conclusions drawn from the nonclinical tests demonstrate that the Branchor X Balloon Guide Catheter is substantially equivalent to the predicate device.