February 2, 2026

ASAHI INTECC CO., LTD.
% Ariel Barret, Ph.D.
Associate Director of Regulatory Affairs
ASAHI INTECC USA, Inc.
22 Executive Park, Suite 110
Irvine, California 92614

Re: K252011
Trade/Device Name: CHIKAI Nexus petit
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF
Dated: December 30, 2025
Received: December 30, 2025

Dear Ariel Barret:

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,
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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)*
K252011

Device Name
CHIKAI Nexus petit

Indications for Use *(Describe)*
This guide wire is intended to be used in the neuro vasculature to facilitate the placement and exchange of therapeutic devices such as cerebral catheters during intravascular therapy. This guide wire is intended for use only in the neuro vasculature.

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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CHIKAI Nexus petit

510(k) K252011

Date Prepared:	30th January, 2026
Applicant:	ASAHI INTECC CO., LTD. 3-100 Akatsuki-cho, Seto, Aichi 489-0071 Japan
Contact:	Ariel Barret, Ph.D. Associate Director of Regulatory Affairs ASAHI INTECC USA, Inc. 22 Executive Park, Suite 110 Irvine, CA 92614 Tel: (240) 4299335 e-mail: aiu_ra@asahi-intecc-us.com
Device Name:	CHIKAI Nexus petit
Device Classification:	Class II, 21 CFR § 870.1330
Classification Name:	Neurovascular Catheter Guide Wire
Product Code:	MOF
Predicate Device:	HYBRID Guidewire (007D, K182337)
Reference Devices:	Balance Middleweight Universal II Guide Wire (K072460) Mirage Hydrophilic Guidewire (008, K201690)

Indications For Use

This guide wire is intended to be used in the neuro vasculature to facilitate the placement and exchange of therapeutic devices such as cerebral catheters during intravascular therapy. This guide wire is intended for use only in the neuro vasculature.

Device Description

The basic structure of the CHIKAI Nexus petit consists of a hybrid tapered core wire in which Ni-Ti alloy and stainless steel (SUS) is conjoined via Ni-Ti pipe. The distal part of the core wire is surrounded by the Pt-Ni (platinum-nickel) coil, soldered with Au-Sn (gold-tin) alloy. For the proximal coil, the joint section is covered by a tube made of Ni-Ti alloy. Within the tube, the stainless steel and Ni-Ti core wires are connected with ASAHI's proprietary stainless-steel coil, soldered with Au-Sn alloy and silver.

In addition, coatings are applied on the surface of the device. The distal coil section is coated with a polyurethane coating. The hydrophilic coating is applied from the distal tip, on top of the polyurethane coating, to the proximal shaft.

The maximum nominal outer diameter of the CHIKAI Nexus petit is 0.33 mm (0.013"). The diameter is tapered towards the distal tip with the nominal diameter of 0.16mm (0.006"). The CHIKAI Nexus petit's radiopaque distal tip (up to 8cm from the tip) enables the user to view the position of the tip under X-ray fluoroscopy. The device is available in length of 220cm with tip-shape variations of Straight, Round-curve and J-shape design.

Accessories

The CHIKAI Nexus petit is packaged with a shaping mandrel, a torque device, and an introducer. The shaping device can be used to facilitate shaping the distal end of the guide wire. The torque device can be attached to the proximal end of the guide wire and used to facilitate the rotation of the guide wire during clinical use. The introducer can be used to assist the insertion of the guide wire into the catheter.

Comparison with Predicate and Reference Devices

The CHIKAI Nexus petit and the predicate and reference devices:

- Have the same intended use and similar indications for use
- Have the same operating principle
- Incorporate the same basic design
- Incorporate the same materials

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

- Use of Pt-Ni coil and Au-Sn solder
- Use of Ni-Ti pipe for core wire connection
- Use of polyurethane coatings
- Different outer diameter.

A tabular comparison of the specific technological characteristics between the subject, predicate, and reference devices is in the table below:

Device Name	CHIKAI Nexus petit	HYBRID Guidewire (007D)	Balance Middleweight Universal II Guide Wire	Mirage Hydrophilic Guidewire (008)
	Subject	Predicate	Reference	
510(k)	K252011	K182337	K072460	K201690
Manufacturer	ASAHI INTECC CO., LTD.	Balt USA, LLC.	Abbott Vascular	Micro Therapeutics, Inc.
Regulation Number	21 CFR 870.1330			
Regulation Name	Catheter, Guide Wire			
Regulatory Class	II			
Product Code	MOF	MOF, DQX	DQX	MOF, DQX
Indications for Use	This guide wire is intended to be used in the neuro vasculature to facilitate the placement and exchange of therapeutic devices such as cerebral catheters during intravascular therapy. This guide wire is intended for use only in the neuro vasculature.	The HYBRID Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The guidewire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in the coronary arteries.	This HI-TORQUE Guide Wire is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). This guide wire may also be used with compatible stent devices during therapeutic procedures.	The Hydrophilic Guidewire is indicated for general intravascular use to aid in the selective placement of catheters in the peripheral, visceral and cerebral vasculature during diagnostic and/or therapeutic procedures.

Device Name	CHIKAI Nexus petit	HYBRID Guidewire (007D)	Balance Middleweight Universal II Guide Wire	Mirage Hydrophilic Guidewire (008)
	Subject	Predicate	Reference	
Nominal Outer Diameter	Max. 0.33mm (0.013”) Min. 0.16mm (0.006”)	Max. 0.30mm (0.012”) Min. 0.18mm (0.007”)	0.36mm (0.014”)	Max. 0.30mm (0.012”) Min. 0.20mm (0.008”)
Overall Length	220cm	120cm, 220cm	190cm, 300cm	200cm
Tapered Core Wire (Distal)	Ni-Ti alloy	Nitinol	Ni-Ti alloy	Stainless-steel
Tapered Core Wire (Proximal)	Austenitic stainless-steel	Stainless-steel	Stainless-steel	Stainless-steel
Coil	Pt-Ni alloy	Platinum Tungsten	Pt-Ni alloy Stainless steel	Platinum
Tip Shape	Straight Round curve J-shape	Straight Double angle	Straight J-tip	Shapeable to 90º
Coating	Hydrophilic coating Polyurethane coating	Hydrophilic coating PTFE	Hydrophilic coating PTFE	Hydrophilic coating
Core joint structure	Ni-Ti pipe and Austenitic stainless-steel	Solder	Ni-Ti pipe	*N/A*
Solder	Au-Sn Ag-Sn	Ag-Sn	Ag-Sn	Unknown
Sterilization	Ethylene oxide (EO) SAL 10^{-6}	Ethylene oxide SAL 10^{-6}	Ethylene oxide SAL 10^{-6}	Ethylene oxide SAL 10^{-6}
Shelf Life	6 Months	5 Years	2 Years	36 Months

Non-Clinical Bench Testing / Performance Data

The following non-clinical bench testing and data for the CHIKAI Nexus petit were provided in support of the substantial equivalence determination. The CHIKAI Nexus petit met all acceptance criteria and performed similarly to the predicate or reference devices.

Test	Test Method Summary	Results/Conclusion
Dimensional Verification	The overall length, outer diameter (coil and shaft), coating lengths of the guide wire are measured.	All samples met the acceptance criteria.
Simulated Use in a Clinically Relevant Model	To simulate clinical use, the test is performed in the anatomical model in accordance with the procedure in Instructions for Use. The guidewire is advanced through the model to the target location, and its performance was evaluated during navigation and removal.	All samples met the acceptance criteria.
Visual Inspection	Test samples are visually inspected to ensure they are free from foreign matter, damage, droplet like residue of coating liquid.	All samples met the acceptance criteria.
Tensile Strength	To determine the tensile strength of the guide wire, the guide wire is fixed in the Tensile Testing Machine and pulled until failure.	All samples met the acceptance criteria.
Torque Strength	To determine the torque strength of the guide wire, distal end is inserted and advanced through simulated model. Distal tip is held stationary while proximal end is rotated until failure.	All samples met the acceptance criteria.
Torqueability	To determine torque response, guidewire is inserted through catheter and into rotational response model. Proximal end is rotated and torque response at distal end is measured.	All samples met the acceptance criteria.
Coating Integrity	To evaluate the coating adhesion and coating integrity of the guidewire, the guidewire surface is visually inspected before and after passing through the tortuous anatomical model.	All samples met the acceptance criteria.
Coating Integrity/Particulate Evaluation in a Clinically Relevant Model	Coating integrity and particulate generation during simulated use in a glass vascular model are evaluated.	The results were comparable to the predicate device.

Lubricity	Lubricity and catheter compatibility is evaluated by measuring slipping resistance of the guide wire against the catheter.	All samples met the acceptance criteria.
Corrosion Resistance	The samples are visually inspected for any sign of corrosion after immersing into aqueous solution of sodium chloride to evaluate for occurrence of corrosion.	All samples met the acceptance criteria.
Kink Resistance	To evaluate the guide wire for resistance to kinking, the guidewire was wound on a jig with clinically-relevant bends followed by microscopic inspection for any damage.	All samples met the acceptance criteria.
Tip Flexibility	To determine the tip flexibility of the guide wire, bending loads of the distal end at various points are measured by applying force at a controlled speed.	All samples met the acceptance criteria.
Radiopacity	The visibility of the distal end of the guidewire is observed under fluoroscopy.	All samples met the acceptance criteria.

Sterilization and Shelf Life

The following tests and evaluations were conducted to validate the sterility and shelf life of the subject device.

Test	Test Method Summary	Results
Sterilization Validation	The sterilization processing group is determined in accordance with AAMI TIR28:2016 Annex A. Subsequently, assurance of a sterility assurance level (SAL) of 10^{-6} is performed in accordance with ISO 11135:2014.	Evaluation justified adoption of the CHIKAI Nexus petit into the EO sterilization processing group. Validation of the EO sterilization cycle was performed using the half-cycle, overkill approach described in ISO 11135:2014, achieving SAL of 10^{-6}.
EO and Ethylene Chlorohydrin (ECH) Residuals	The evaluation of EO and ECH residuals determined that EO and ECH residuals data for the CHIKAI Nexus petit can be adopted from the existing validated product data and results of accessories were measured per AAMI/ANSI/ISO 10993-7:2008.	The residuals of EO and ECH in the CHIKAI Nexus petit and its accessories after exposure to the EO sterilization process met the required limits in AAMI/ANSI/ISO 10993-7:2008.
Bacterial Endotoxin Levels	Limulus amebocyte lysate (LAL) testing was conducted in accordance with ANSI/AAMI ST72:2011/(R) 2016, USP <161>, and USP <85>, using the kinetic chromogenic method.	The CHIKAI Nexus petit and its accessories met the acceptance criteria of <2.15 endotoxin units (EU) / device.
Shelf Life	Device performance attributes that can be affected by aging and storage conditions were evaluated after exposure to accelerated aging conditions per ASTM F1980. Package integrity of the CHIKAI Nexus petit and its accessories was validated by leveraging the results of representative samples which were tested according to ISO 11607-1.	After exposure to accelerated aging conditions simulating real-time storage under ambient conditions for 6 months, all device performance acceptance criteria were met and evaluation of packaging integrity satisfied the criteria, justifying labeling the devices, with a 6-month shelf life.

Biocompatibility

The CHIKAI Nexus petit 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*"," and found to be biocompatible.
The indirect-contacting accessory was evaluated and found to be biocompatible by leveraging the data of legally marketed devices.

Test	Test Summary	Conclusion
Cytotoxicity MEM Elution Test	Determine the potential cytotoxicity of a mammalian cell culture (L929) in response to the test article extract.	Non-Cytotoxic
Sensitization Kligman Maximization Test	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	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 Test	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	Determine the potential presence of material-mediated pyrogen.	Non-Pyrogenic
Hemocompatibility Rabbit Blood Hemolysis Test	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 SC5b-9 Complement Activation Test	Human plasma was exposed to the device (direct contact) to determine the potential activation of the SC5b-9 complement system.	Non-Activator
Hemocompatibility Partial Thromboplastin Time Test (PTT)	Human plasma was exposed to the device (direct contact) to assess any effect on the intrinsic coagulation pathway by measuring clotting time.	Non- Activator
Hemocompatibility Platelet and Leukocyte Count Test (PLC) (Direct Contact)	Compared and evaluated the thrombogenicity properties and surface characteristics of direct blood contacting components of the subject and predicate device *in vitro.*	Subject device was not considered to have an effect on thrombogenicity.

Conclusion

The CHIKAI Nexus petit and the predicate device share the same intended use and similar technological characteristics. Differences in technological characteristics between the subject and predicate devices do not raise different questions of safety or effectiveness. Non-clinical tests demonstrate that the subject device performs as intended. Therefore, the CHIKAI Nexus petit is substantially equivalent to the predicate device.