April 21, 2025

ASAHI INTECC CO., LTD.
℅ Cynthia Valenzuela
Director, Regulatory Affairs
ASAHI INTECC USA, INC.
3002 Dow Avenue, Suite 212
Tustin, California 92780

Re: K243383
Trade/Device Name: CHIKAI Nexus 014
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF
Dated: March 19, 2025
Received: March 19, 2025

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 (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)*
K243383

Device Name
CHIKAI Nexus 014

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

[As required by 21 CFR § 807.92(c)]

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CHIKAI Nexus 014

510(k) __K243383___

DATE PREPARED:	14th April 2025
APPLICANT:	ASAHI INTECC CO., LTD. 3-100 Akatsuki-cho, Seto Aichi 489-0071, Japan
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TRADE NAME:	CHIKAI Nexus 014
DEVICE CLASSIFICATION:	Class II, 21 CFR § 870.1330
CLASSIFICATION NAME:	Neurovascular Catheter Guide Wire
PRODUCT CODE:	MOF
PREDICATE DEVICE(S):	ASAHI Neurovascular Guide Wire CHIKAI black (K141751)
REFERENCE DEVICE(S):	ASAHI PTCA Guide Wire Soft (K022762, K163426) ASAHI Neurovascular Guide Wire CHIKAI Round Curve (K160659) ASAHI Neurovascular Guide Wire CHIKAI X 014 soft (K191714)

Intended Use/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 CHIKAI Nexus 014 consists of a stainless-steel tapered core wire, with an inner coil and outer coil made of radiopaque Pt-Ni alloy and stainless-steel. Surrounding the inner coil and the distal core wire is a radiopaque Pt-Ni alloy and stainless-steel outer coil. The radiopaque distal tip enables the user to view the position of the tip under X-ray fluoroscopy. Outer and inner coils are soldered to the tapered core wire with Ag-Sn solder. A similar coil design is used with other ASAHI guide wires, such as the predicate CHIKAI black (K141751).

Additionally, the CHIKAI Nexus 014 employs hydrophilic, polyurethane, PTFE, and silicone coatings which are used in the predicate and reference devices.

The nominal outer diameter of the CHIKAI Nexus 014 is 0.36 mm (0.014 inch). The device is available in two lengths: 215 cm and 300 cm.
Both sizes are available with straight, pre-shape, and angled designs.

Accessories
CHIKAI Nexus 014 is packaged with a shaping device, torque device, and inserter.
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 inserter device can be used to assist the insertion of guide wire into the catheter.

Comparison with Predicate and Reference Devices
The subject, predicate, and reference devices:

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

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

- Different inner coil structure
- Different lineup of usable length
- Different coating length

Device name	**CHIKAI Nexus 014**	**CHIKAI black**	**PTCA Guide Wire Soft**	**CHIKAI Round Curve**	**CHIKAI X 014 soft**
	Subject	Predicate	Reference		
510(k)	K243383	K141751	K022762 K163426	K160659	K191714
Manufacturer	ASAHI INTECC				
Regulation Number	21 CFR 870.1330				
Regulation Name	Catheter Guide Wire				
Regulatory Class	II				
Product code	MOF	MOF	DQX	MOF	MOF
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.	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.	ASAHI PTCA Guide Wires are intended to facilitate the placement of balloon dilation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The ASAHI PTCA Guide Wires are not to be used in the neurovasculature.	ASAHI CHIKAI Neurovascular 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 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.

	CHIKAI Nexus 014	**CHIKAI black**	**PTCA Guide Wire Soft**	**CHIKAI Round Curve**	**CHIKAI X 014 soft**
Nominal Outer Diameter	0.36 mm (0.014 inch)	0.36 mm (0.014 inch)	0.36 mm (0.014 inch)	0.36 mm (0.014 inch)	0.36 mm (0.014 inch)
Overall Length	215 cm, 300 cm	200 cm, 300 cm	180 cm, 300 cm	200 cm, 300 cm	200 cm
Outer Coil	Austenitic stainless-steel Pt-Ni alloy	Austenitic stainless-steel Pt-Ni alloy	Austenitic stainless-steel Pt-Ni alloy	Austenitic stainless-steel Pt-Ni alloy	Austenitic stainless-steel
Tapered Core Wire	Austenitic stainless-steel	Austenitic stainless-steel	Austenitic stainless-steel	Austenitic stainless-steel	Austenitic stainless-steel
Inner Coil	Austenitic stainless-steel Pt-Ni alloy	Austenitic stainless-steel	N/A	Austenitic stainless-steel	Pt-Ni alloy
Tip Shape	Straight, Pre-shape, Angled	Round Curve, Angled	Straight	Round Curve,	Straight
Coating	Hydrophilic Silicone Polyurethane PTFE	Hydrophilic Polyurethane PTFE* *applicable to 300 cm model only	Silicone PTFE	Hydrophilic PTFE* *applicable to 300 cm model only	Hydrophilic Silicone
Solder	Ag-Sn	Ag-Sn	Ag-Sn	Ag-Sn	Ag-Sn
Sterilization	Ethylene oxide (EO) Sterility assurance level (SAL) 10^{-6}	EO SAL 10^{-6}	EO SAL 10^{-6}	EO SAL 10^{-6}	EO SAL 10^{-6}
Shelf Life	6 months	3 years	3 years	3 years	3 years

Sterility and Shelf Life

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

Test	Test Method Summary	Results
Sterilization Validation	100% EO is used to sterilize the device to achieve a SAL of at least 10^{-6}. The device was adopted into an EO sterilization processing group in accordance with AAMI TIR28:2016. Validation of the EO sterilization cycle was performed using the half-cycle, overkill approach described in ISO 11135:2014.	Results of evaluation by AAMI TIR28 justified adoption of the CHIKAI Nexus 014 into the EO sterilization processing group. Additional testing was conducted to validate and ensure sterilization.
EO and ECH Residuals	Measured EO and ethylene chlorohydrin (ECH) residuals per AAMI/ANSI/ISO 10993-7:2008.	The residual traces of EO and ECH remaining in the CHIKAI Nexus 014 after exposure to the EO sterilization process met the appropriate criteria with sufficient aeration time.
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 014 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 014 was validated by leveraging the results of previously cleared ASAHI INTECC's guide wires 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.

Non-Clinical Testing / Performance Data

The substantial equivalence of the CHIKAI Nexus 014 was evaluated in bench testing that followed the recommendations in the FDA guidance document, "*Coronary, Peripheral, and Neurovascular Guidewires - Performance Tests and Recommended Labeling*," October 2019.

Test	Test Method Summary	Results/Conclusion
Dimensional Verification	The overall length, outer diameters (coil and shaft), and coating lengths of the guidewire are measured.	All samples met the acceptance criteria.
Simulated Use	To simulate clinical use, the test is performed in a clinically relevant model in accordance with the procedure in the Instructions for Use. The guidewire is advanced through the model to the target location, and its performance is evaluated during navigation and removal.	All samples met the acceptance criteria.
Visual Inspection	Test samples are visually inspected for foreign matter, damage, droplet like residue of coating liquid.	All samples met the acceptance criteria.
Tensile Strength	To determine the tensile strength of the guidewire, the guidewire 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 guidewire, 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 winding the guidewire around a clinically relevant-sized test jig.	All samples met the acceptance criteria.
Coating Integrity/ Particulate Evaluation	Coating integrity and particulate generation during simulated use in a glass vascular model are evaluated. Testing follows GLP conditions and relevant FDA guidance.	The results were comparable to the predicate device.
Lubricity	Lubricity and catheter compatibility is evaluated by measuring slipping resistance of the guidewire 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.	All samples met the acceptance criteria.
Kink Resistance	The guidewire kink resistance is evaluated by performing multiple bends of clinically relevant radii followed by microscopic inspection for any damage.	All samples met the acceptance criteria.
Tip Flexibility	To determine the tip flexibility of the guidewire, 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 evaluated under fluoroscopy.	All samples met the acceptance criteria.

The *in vitro* bench tests demonstrated that the CHIKAI Nexus 014 met all acceptance criteria and performed similarly to the predicate device. Performance data demonstrate that the device functions as intended and has a safety and effectiveness profile that is similar to the predicate device.

BIOCOMPATIBILITY

The biocompatibility of CHIKAI Nexus 014 was evaluated in accordance with ISO 10993 series of standards:

Test	Test Method Summary	Results/Conclusion
Cytotoxicity ISO 10993-5 MEM Elution Test	Determine the potential cytotoxicity of a mammalian cell culture (L929) in response to the test article extract.	Non-cytotoxic
Sensitization ISO 10993-10 Kligman Maximization Test	Allergenic or sensitizing potential of the device was evaluated using polar and non-polar extracts in a guinea pig maximization test.	Negative for sensitization
Irritation ISO 10993-23 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-irritating; Sites injected with the extracts of the subject device did not show a significantly greater biological reaction than the sites injected with control article (predicate device).
Systemic Toxicity ISO 10993-11 Acute 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
Systemic Toxicity ISO 10993-11 USP <151> Rabbit Pyrogen Test (Material Mediated)	Determine the potential presence of material-mediated pyrogen.	Non-pyrogenic
Hemocompatibility ISO 10993-4 Rabbit Blood Direct and Indirect (Extract) Hemolysis	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 in both direct and indirect hemolysis tests

Hemocompatibility ISO 10993-4 Complement Activation (SC5b-9)	Human plasma was exposed to the device (direct contact) to determine the potential activation of the SC5b-9 complement system.	Non-activator; The concentration of SC5b-9 in the plasma exposed to the device was not statistically different from those of negative and untreated control.
Hemocompatibility ISO 10993-4 Thrombogenicity	Compared and evaluated the thrombogenicity properties of direct blood contacting components of the subject and predicate devices *in vivo.*	Subject and predicate devices showed similar thrombogenic potential.

CONCLUSION:

The CHIKAI Nexus 014 has the same intended use and the same or similar technological characteristics, such as components, design, materials, sterilization method, and operating principles as the predicate device. The differences between the subject and predicate device do not raise different or new questions of safety or effectiveness.

Performance data demonstrate that the device functions as intended. Therefore, the CHIKAI Nexus 014 is substantially equivalent to the predicate device.