August 14, 2024

Asahi Intecc Co., Ltd.
Cynthia Valenzuela
Director, Quality Systems, Regulatory Affairs/Compliance
3002 Dow Avenue
Suite 212
Tustin, California 92780

Re: K241510
Trade/Device Name: CROSSLEAD Tracker
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: July 15, 2024
Received: July 15, 2024

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.

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,

Lydia S. Glaw -S

Digitally signed by Lydia S. Glaw -S
Date: 2024.08.14 16:22:50 -04'00'

Lydia Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241510

Device Name
CROSSLEAD Tracker

Indications for Use *(Describe)*
This product is designed to direct a catheter to the desired anatomical location in the peripheral vasculature during diagnostic or interventional procedures. Do not use the guide wire in neurovascular.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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)

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CROSSLEAD Tracker

510(k) K241510

Date Prepared:	27 MAY 2024
Applicant:	ASAHI INTECC CO., LTD. 3-100 Akatsuki-cho, Seto, Aichi 489-0071 Japan
Contact:	C. Cynthia Valenzuela Director, Quality and Regulatory Affairs ASAHI INTECC USA, Inc. 3002 Dow Avenue, Suite 212 Tustin, CA 92780 Tel: (949) 745-1617 e-mail: cynthiav@asahi-intecc-us-.com
Trade Name:	CROSSLEAD Tracker
Device Classification:	Class 2 per 21 CFR § 870.1330
Classification Name:	Catheter, Guide, Wire
Product Code:	DQX – Catheter Guide Wire
Predicate Device:	Regalia XS 1.0 K083146/K163426
Reference Devices:	MINAMO K190176 ASAHI Gaia Next K192599 ASAHI Gladius K150445/K163426

INTENDED USE/INDICATIONS FOR USE:

This product is designed to direct a catheter to the desired anatomical location in the peripheral vasculature during diagnostic or interventional procedures.
Do not use the guide wire in neurovascular.

DEVICE DESCRIPTION:

The CROSSLEAD Tracker is steerable guide wire with a maximum diameter of 0.014 inches (0.36mm) and available in 100cm, 200cm, 235cm and 300cm length. This Guide Wire consists of a hybrid Ni-Ti and stainless-steel core wire with a Pt-Ni inner coil and Pt-Ni and stainless-steel outer coil. The coil is soldered to the core wire with Ag-Sn solder. The coil has radiopacity to achieve visibility and can be made to bend easily with the vessel curve. A hydrophilic coating is applied to the distal portion of the guide wire. A hydrophobic coating is applied to proximal portion. The basic structure, construction, and material of the CROSSLEAD Tracker are similar to that previously described in the predicate Regalia XS 1.0 (K083146/K163426) and reference devices MINAMO (K190176), ASAHI Gaia Next(K192599) and ASAHI Gladius (K150445/K163426).

COMPARISON WITH PREDICATE AND REFERENCE DEVICES:

Comparisons of the CROSSLEAD Tracker and predicate / reference devices show that the technological characteristics of the subject device such as the components, design, materials, sterilization method, shelf life and operating principle are similar to the currently marketed predicate and reference devices. The intended use of the subject device and its predicates are the same.

Name of Devices	**CROSSLEAD Tracker**	**Regalia XS 1.0**	**MINAMO**	**Gaia Next**	**ASAHI Gladius**
	Subject	Predicate	Reference	Reference	Reference
510(k)	TBD	K083146,K163426	K190176	K192599	K150445,K163426
Intended Use and Indications	This product is designed to direct a catheter to the desired anatomical location in the peripheral vasculature during diagnostic or interventional procedures. Do not use the guide wire in neurovascular.	ASAHI Peripheral Guide Wires are intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is intended for peripheral vascular use only.	PCI Guide Wires are intended to facilitate the placement of balloon dilatation catheters during percutaneous coronary intervention (PCI) and percutaneous transluminal angioplasty (PTA). The PCI Guide Wires are not intended for use in the neurovasculature.	ASAHI PTCA Guide Wires are intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA), including use in crossing or assisting in crossing de novo coronary chronic total occlusions (CTO) The ASAHI PTCA Guide Wires are not to be used in the neurovasculature.	ASAHI Peripheral Guide Wires are intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is intended for peripheral vascular use only.
Nominal OD	0.36mm (0.014inch)	0.36mm (0.014inch)	0.36mm (0.014inch)	0.36mm (0.014inch)	0.46mm(0.018inch) 0.36mm(0.014inch)
Overall Length	100, 200, 235,300 cm	180, 300cm	190, 300cm	190 cm	200cm, 235cm,300cm
Outer Coil	Platinum-Nickel and Stainless Steel	Platinum-Nickel and Stainless Steel	Platinum-Nickel and Stainless Steel	Platinum-Nickel and Stainless Steel	Platinum-Nickel and Stainless Steel

Name of Devices	CROSSLEAD Tracker	Regalia XS 1.0	MINAMO	Gaia Next	ASAHI Gladius
Tapered Core Wire	Nitinol and Stainless Steel	Stainless Steel	Nitinol and Stainless Steel	Stainless Steel	Stainless Steel
Inner Coil	Platinum-Nickel and Stainless Steel		Stainless Steel	Platinum-Nickel and Stainless Steel	Stainless Steel
Tip Shape	Straight, Pre-shape	Straight J-tip	Straight Pre-shape J-tip	Pre-shape	Straight Pre-shape
Coating	Hydrophilic Hydrophobic	Hydrophilic Hydrophobic	Hydrophilic Hydrophobic	Hydrophilic Hydrophobic	Hydrophilic Hydrophobic
Sterilization	Provided sterile via Ethylene Oxide	Provided sterile via Ethylene Oxide	Provided sterile via Ethylene Oxide	Provided sterile via Ethylene Oxide	Provided sterile via Ethylene Oxide

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

- Coil structure
- Core shaft

NON-CLINICAL TESTING/PERFORMANCE DATA:

Non-clinical laboratory testing was performed on the CROSSLEAD Tracker to determine substantial equivalence. The following testing/assessments were performed:

- Tensile Strength
- Torque Strength
- Torqueability
- Tip Flexibility
- Coating Integrity
- Catheter Compatibility
- Visual Inspection
- Corrosion Resistance
- Kink Resistance
- Radio – Detectability
- Dimensional Verification
- Coating Integrity / Acute Particulate Characterization

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

BIOCOMPATIBILITY:

Testing was performed to assess biocompatibility of the modified coating material.
The following tests were performed:

- Cytotoxicity
- Sensitization
- Intracutaneous Irritation
- Systemic Toxicity
- USP Rabbit Pyrogen, Material Mediated
- Hemolysis
- Partial Thromboplastin Time
- In Vivo Thromboresistance
- Sc5b-9 Complement Activation

CONCLUSION:

The CROSSLEAD Tracker has the same intended use and the same or similar technological characteristics such as components, design, materials, sterilization method, shelf life and operating principles as the predicate and reference devices. Performance data demonstrates that the device functions as intended.

Therefore, the CROSSLEAD Tracker is substantially equivalent to the predicate and reference devices.