February 6, 2025

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

Re: K241702
Trade/Device Name: CROSSLEAD 0.014inch
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: January 7, 2025
Received: January 7, 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,

Samuel G. Raben -S

for 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241702

Device Name
Crosslead 0.014 inch

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 21CFR § 807.92(c)]

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CROSSLEAD 0.014inch

510(k) K241702

DATE PREPARED:	11 JUNE 2024
APPLICANT:	ASAHI INTECC CO., LTD. 3-100 Akatsuki-cho, Seto Aichi 489-0071, Japan
PRIMARY CONTACT:	Cynthia Valenzuela Director, Quality and Regulatory 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
DEVICE CLASSIFICATION:	Class II, 21CFR § 870.1330
CLASSIFICATION NAME:	Catheter Guide Wire
PRODUCT CODE:	DQX
PREDICATE DEVICE(S):	ASAHI Gladius (K150445/K163426)
REFERENCE DEVICE(S):	CROSSLEAD Penetration (K230377) MINAMO (K190176) Astato XS 40 (K153443/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 0.014inch is steerable guide wire with a maximum diameter of 0.014inch (0.36mm) and available in various lengths of 100cm, 200cm, 235cm and 300cm. This guide wire consists of a hybrid nitinol (Ni-Ti) and stainless-steel (SUS) core wire with a stainless-steel inner coil and Platinum-Nickel (Pt-Ni) outer coil. The coil is radiopaque 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 materials of the CROSSLEAD 0.014inch are similar to those of previously described in the predicate ASAHI Gladius (K150445/K163426) and references; CROSSLEAD Penetration (K230377), MINAMO (K190176) and Astato XS40 (K153443/K163426).

All sizes are available with a straight and a pre-shaped design.

COMPARISON WITH PREDICATE AND REFERENCE DEVICES:

Comparisons of the CROSSLEAD 0.014inch 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 0.014inch**	**ASAHI Gladius**	**CROSSLEAD Penetration**	**MINAMO**	**Astato XS 40**
	Subject	Predicate	Reference		
510(k)	TBD	K150445/K163426	K230377	K190176	K153443/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.	This product is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is intended for peripheral vascular use only.	This product is designed to direct a catheter to the desired anatomical location in the peripheral vasculature during diagnostic or interventional procedures.	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.	This product is 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	0.36 mm (0.014”)	0.36mm (0.014”) 0.46mm (0.018”)	0.36mm (0.014”) 0.46mm (0.018”)	0.36 mm (0.014”)	0.36 mm (0.014”) tapering to 0.023 (0.009”) Tip
Overall Length	100cm, 200cm, 235cm, 300 cm	200cm, 235cm, 300cm	200cm, 235cm, 300cm	190 cm, 300 cm	200 cm, 300 cm
Outer Coil	Platinum-Nickel	Platinum-Nickel and Stainless Steel	Platinum-Nickel	Platinum-Nickel and Stainless Steel	Platinum-Nickel

Name of Devices	**CROSSLEAD 0.014inch**	**ASAHI Gladius**	**CROSSLEAD Penetration**	**MINAMO**	**Astato XS 40**
Tapered Core Wire	Nitinol and Stainless steel	Stainless Steel	Stainless Steel	Nitinol and Stainless steel	Stainless steel
Inner Coil	Stainless steel	Stainless steel	N/A	Stainless steel	N/A
Tip Shape	Straight, Pre-shape	Straight, Pre-shape	Straight, Pre-shape	Straight, Pre-shape, J shape	Straight
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 shape

NON-CLINICAL TESTING/PERFORMANCE DATA:

Non-clinical laboratory testing was performed on the CROSSLEAD 0.014inch 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 0.014inch 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:

The biocompatibility of the CROSSLEAD 0.014inch had been confirmed in regards to the following aspects.

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

CONCLUSION:

The CROSSLEAD 0.014inch 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 0.014inch is substantially equivalent to the predicate.