March 5, 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: K242597
Trade/Device Name: CROSSLEAD 0.018inch
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: August 30, 2024
Received: August 30, 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.

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,

Jenny R. Katsnelson -S

Digitally signed by Jenny R. Katsnelson -S
Date: 2025.03.05 23:14:13 -05'00'

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242597

Device Name
CROSSLEAD 0.018inch

Indications for Use *(Describe)*
This product is intended to direct a catheter to the desired anatomical location in the peripheral vasculature (excluding coronary and cerebral vessels) during diagnostic or interventional procedures.

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.

510(k) Summary

(as required by 21 CFR § 807.92)

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CROSSLEAD 0.018inch

510(k) 242597

Date Prepared:	30 AUG 2024
Applicant:	ASAHI INTECC CO., LTD. 3-100 Akatsuki-cho, Seto, Aichi 489-0071 Japan
Contact:	Mrs. 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 0.018 inch
Device Classification:	Class 2 per 21 CFR § 870.1330
Classification Name:	Catheter, Guide, Wire
Product Code:	DQX – Catheter Guide Wire
Predicate Device:	Gladius Mongo18 PV ES K213868
Reference Devices:	CROSSLEAD Tracker K241510 CROSSLEAD Penetration K230377 V-18 Control Wire K033742

INTENDED USE/INDICATIONS FOR USE:

This product is designed to direct a catheter to the desired anatomical location in the peripheral vasculature (excluding coronary and cerebral vessels) during diagnostic or interventional procedures.

DEVICE DESCRIPTION:

The CROSSLEAD 0.018inch is steerable guide wire with a maximum diameter of 0.46mm (0.018inches) and available in various lengths of 100 cm, 200 cm, 235 cm and 300 cm. The guide wire consists of a hybrid nitinol (Ni-Ti) and stainless-steel (SUS) core wire with a stainless steel inner coil, a stainless steel and Platinum-Nickel (Pt-Ni) outer coil. The coil is radiopaque to achieve visibility and can be made to bend easily to accommodate vessel tortuosity. A hydrophilic and polyurethane coating are applied to the distal portion of the guide wire. A hydrophobic coating (PTFE) is applied to proximal portion. The purpose of these surface coatings is to provide lubricity when the guide wire is passed through percutaneous catheters.

The basic structure, construction and materials of the CROSSLEAD 0.018inch are similar to those of the predicate Gladius Mongo18 PV ES (K213868), and the references CROSSLEAD Penetration (K230377), CROSSLEAD Tracker (K241510) and V-18 Control Wire (K033742).

COMPARISON WITH PREDICATE AND REFERENCE DEVICES:

The following comparison table of the CROSSLEAD 0.018inch and the predicate/reference devices indicates that the technological characteristics of the subject device such as the components, design, materials, sterilization method and operating principle are similar. The intended use of the CROSSLEAD 0.018inch and its predicate device is also comparable.

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

- Outer Coil structure
- Core shaft structure

Device name	Subject	Predicate	References		
	CROSSLEAD 0.018inch	Gladius Mongo18 PV ES	CROSSLEAD Tracker	CROSSLEAD Penetration	V-18 Control Wire
510(k)	TBD	K213868	K241510	K230377	K033742
Manufacturer	ASAHI INTECC CO., LTD.				Boston Scientific
Intended and/or Indication for Use	This product is intended to direct a catheter to the desired anatomical location in the peripheral vasculature (excluding coronary and cerebral vessels) during diagnostic or interventional procedures.	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. Do not use the guide wire in neurovascular.	This product is designed to direct a catheter to the desired anatomical location in the peripheral vasculature during diagnostic or interventional procedures.	The 110cm V-18 Control Wire is intended for general intravascular use including the placement of PTA balloon catheters requiring an 0.018" guide wire in hemodialysis AV access procedures. The wire can be torqued to facilitate placement of diagnostic or therapeutic catheters. This device is intended for peripheral vascular use only. A torque device is included with each wire to facilitate directional manipulation of the guide wire.

Device name	Subject	Predicate	References		
	CROSSLEAD 0.018inch	Gladius Mongo18 PV ES	CROSSLEAD Tracker	CROSSLEAD Penetration	V-18 Control Wire
Nominal OD	0.46mm (0.018”)	0.46mm (0.018”)	0.36mm (0.014”)	0.36mm(0.014”) 0.46mm(0.018”)	0.46mm (0.018”)
Usable Length	100cm, 200cm, 235cm, 300cm	190cm, 235cm, 300cm	100cm, 200cm, 235cm, 300cm	200cm, 235cm, 300cm	110cm, 150cm, 200cm, 300cm
Outer Coil	Austenitic Stainless Steel Pt-Ni alloy	Pt-Ni alloy	Austenitic Stainless Steel Pt-Ni alloy	Pt-Ni alloy	unknown
Inner Coil	Austenitic Stainless Steel	Austenitic Stainless Steel	Pt-Ni alloy	-	unknown
Taper Core Wire	Ni-Ti alloy Austenitic Stainless Steel	Austenitic Stainless Steel	Ni-Ti alloy Austenitic Stainless Steel	Austenitic Stainless Steel	Stainless Steel
Tip Shape	Straight, Pre-shape	Straight, Pre-shape	Straight, Pre-shape	Straight, Pre-shape	Straight
Coating	Hydrophilic Polyurethane PTFE	Hydrophilic Polyurethane PTFE	Hydrophilic Polyurethane PTFE	Hydrophilic PTFE	Hydrophilic PTFE Polyurethane Polymer
Solder	Ag-Sn Au-Sn	Ag-Sn Au-Sn	Ag-Sn Au-Sn	Au-Sn	unknown
Sterilization	Ethylene oxide SAL 10^{-6}	Ethylene oxide SAL 10^{-6}	Ethylene oxide SAL 10^{-6}	Ethylene oxide SAL 10^{-6}	unknown

NON-CLINICAL TESTING/PERFORMANCE DATA:

Non-clinical laboratory testing was performed on the CROSSLEAD 0.018inch to determine substantial equivalence. The following testing/assessments were conducted:

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

The *in vitro* bench tests demonstrated that the CROSSLEAD 0.018inch met all acceptance criteria and performed similarly to the predicate and reference devices. Performance data demonstrates the CROSSLEAD 0.018inch functions as intended and has a safety and effectiveness profile that is similar to the predicate and reference devices although there are the technological differences between the subject and predicate/reference devices.

BIOCOMPATIBILITY:

The biocompatibility of the CROSSLEAD 0.018inch had been confirmed in regards to the following aspects.

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

CONCLUSION:

The CROSSLEAD 0.018inch and the predicate/reference devices share the same intended use and the same or similar technological characteristics such as components, design, materials, sterilization method and operating principles. Differences in technological characteristics between the subject and predicate/reference devices do not raise different questions of safety and effectiveness. Non- clinical tests demonstrate that the device has a similar safety and effectiveness profile as the legally marketed predicate/reference devices. Therefore, ASAHI considers the CROSSLEAD 0.018inch to be substantially equivalent to the predicate and reference devices.