July 1, 2022

Asahi Intecc Co., LTD.
% Cynthia Valenzuela
Director, Regulatory Affair
Asahi Intecc USA, Inc.
3002 Dow Avenue, Suite 212
Tustin, California 92780

Re: K213315
Trade/Device Name: CROSSLEAD Peripheral Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: May 20, 2022
Received: May 24, 2022

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

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)*

K213315

Device Name

CROSSLEAD Peripheral Guide Wire

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.

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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)]

**Global Headquarters and R&D Center**
**3-100 Akatsuki-cho, Seto-shi, Aichi 489-0071 Japan**
**TEL : +81-561-48-5551 FAX : +81-561-48-5552**
**http://www.asahi-intecc.co.jp/**

# CROSSLEAD Peripheral Guide Wire

**510(K)** __K_____

| | |
|---|---|
| **DATE PREPARED:** | |
| **APPLICANT:** | ASAHI INTECC CO., LTD.<br>3-100 Akatsuki-cho, Seto<br>Aichi 489-0071, Japan |
| **PRIMARY CONTACT:** | Mrs. Cynthia Valenzuela<br>Director, Regulatory Affairs<br>ASAHI INTECC USA, INC.<br>3002 Dow Avenue, Suite 212<br>Tustin, California 92780<br>Phone: (714) 442 0575<br>Fax: (949) 377 3255<br>Email: cynthiav@asahi-intecc-us.com |
| **ALTERNATE CONTACT:** | Mr. Yoshi Terai<br>President, CEO<br>ASAHI INTECC USA, INC.<br>Tustin, CA 92780 USA<br>Phone: (949) 756 8901<br>Fax: (949) 377 3255<br>Email: yoshi@asahi-intecc-us.com |
| **TRADE NAME:** | CROSSLEAD Peripheral Guide Wire |
| **DEVICE CLASSIFICATION:** | Class II, 21CFR § 870.1330 |
| **CLASSIFICATION NAME:** | Catheter Guide Wire |
| **PRODUCT CODE:** | DQX |
| **PREDICATE DEVICE(S):** | Radifocus Glidewire Advantage (K063372) |
| **REFERENCE DEVICE(S):** | ASAHI Silverway (K183062)<br>ASAHI Regalia XS 1.0 (K083146)<br>Emerald guidewire (K935170)<br>MINAMO (K190176) |

**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.*

**Description:**
The CROSSLEAD Peripheral Guide Wire (hereafter “CROSSLEAD”) is a steerable guide wire with a maximum diameter of 0.035 inches (0.89mm) and available in 200cm and 300cm length. The guide wire is constructed from a Ni-Ti alloy core wire with a stainless steel 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 coating of the CROSSLEAD are unchanged from that previously described in the predicate Radifocus Glidewire Advantage (K063372) and reference ASAHI Silverway (K183062) and ASAHI Regalia XS 1.0 (K083146)

**Accessory**
The CROSSLEAD is packaged with a shaping needle.
The shaping needle can be used to facilitate shaping of the guide wire distal end. The shaping needle consists of a stainless-steel needle, a polypropylene hub and polyethylene cover.

**Comparison with Predicate Device and Reference Device:**

| Predicate | Device Name | 510(K) Number |
|---|---|---|
| Primary Predicate | Radifocus Glidewire Advantage | K063372 |
| Reference Device | ASAHI Silverway | K183062 |
| Reference Device | ASAHI Regalia XS 1.0 | K083146 |
| Reference Device | Emerald guidewire | K935170 |
| Reference Device | MINAMO | K190176 |

The subject device has the following similarities to those which previously received 510(k) clearance.

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

Comparison with Predicate Device and Reference Device

| **Name of Devices** | **CROSSLEAD** | **Radifocus Glidewire Advantage** | **ASAHI Silverway** | **ASAHI Regalia XS 1.0** |
|---|---|---|---|---|
| | Subject | Predicate | Reference | Reference |
| 510(k) | TBD | K063372 | K183062 | K083146 |
| Manufacturer | ASAHI INTECC | TERUMO | ASAHI INTECC | ASAHI INTECC |
| Classification Regulation | 21 CFR 830.1330, Cardiovascular | | | |
| Common Name | Catheter Guide Wire | | | |
| Product Code | DQX | | | |
| Class | II | | | |
| Intended Use | Guide wire for percutaneous intervention | | | |
| 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. | The Radifocus Glidewire Advantage is designed to direct catheter to the desired anatomical location during diagnostic or interventional procedures. | This product is intended to be used for the adjustment of the position of interventional devices in a blood vessel and as an aid in moving the catheter. It is not for use in coronary arteries or intracranial vessels. | 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 | 0.89mm (0.035inch) | 0.36mm (0.014inch)<br>0.45mm (0.018inch)<br>0.89mm (0.035inch) | 0.89mm (0.035inch) | 0.36mm (0.014inch) |
| Overall Length | 200cm, 300cm | 180cm, 260cm, 300cm | 150cm, 180cm, 200cm<br>220cm, 260cm, 300cm | 180cm, 300cm |
| Outer Coil | SUS | Gold | SUS | Pt-Ni and SUS |
| Core Wire | Ni-Ti alloy | Nitinol alloy | SUS | SUS |
| Tip Shape | Straight, Angled | 45°Angle | Angled, J-Shape (1.5mm),<br>J-Shape (3.0mm) | Straight |
| Coating | <Distal> Hydrophilic<br><Proximal> Hydrophobic | <Distal> Hydrophilic<br><Proximal> Hydrophobic | <Distal, Proximal><br>Hydrophobic<br><Middle> Hydrophilic | <Distal> Hydrophilic<br><Proximal> Hydrophobic |
| Sterilization | Provided sterile via Ethylene Oxide to SAL $10^{-6}$ | Provided sterile via Ethylene Oxide to SAL $10^{-6}$ | Provided sterile via Ethylene Oxide to SAL $10^{-6}$ | Provided sterile via Ethylene Oxide to SAL $10^{-6}$ |

**Non Clinical Testing / Performance Data:**
The substantial equivalence of the CROSSLEAD was evaluated in bench testing that followed the recommendations in the FDA guidance document; *Coronary, Peripheral, and Neurovascular Guidewires - Performance Tests and Recommended Labeling*, 15JUN2018.

- Tensile Strength
- Torque Strength
- Torqueability
- Tip Flexibility
- Coating Adhesion / Integrity
- Catheter Compatibility
- Appearance and Cleanliness
- Corrosion Resistance
- Kink Resistance
- Radio - detectability
- Dimensional Verification

The in vitro bench tests demonstrated that the CROSSLEAD met all acceptance criteria and performed similarly to the predicate devices. 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 CROSSLEAD was tested in accordance with ISO 10993, and found to be biocompatible. The following tests were performed:

**Biocompatibility Results (brief)**

| Test | Test Summary | Conclusion |
|---|---|---|
| **Cytotoxicity -** ISO 10993-5 L929 cells/MEM Elution Test | The test system is considered suitable if no signs of cellular reactivity (Grade 0) are noted for both the negative control article and the medium control. | Non-cytotoxic |
| **Sensitization -** ISO 10993-10 KLIGMAN Maximization Test | The extracts should show no evidence of causing delayed dermal contact sensitization in the guinea pig. | Non-sensitizing |
| **Irritation -** ISO 10993-10 Intracutaneous Injection Test | The test extract and the negative control must exhibit similar edema and erythema scores. | Non-irritant |
| **Systemic Toxicity -** ISO 10993-11 Acute System Toxicity Test | The test article must not show significantly greater biological activity than the control. | No Systemic Toxicity |
| **Systemic Toxicity -** ISO 10993-11 Rabbit Pyrogen Test (material mediated) | The test article should not increase the rectal temperature of any of the animals by more than 0.5 degrees Celsius. | Non-pyrogenic |
| **Hemocompatibility -** ISO 10993-4 Rabbit Blood Hemolysis Test | Test article in direct contact with blood and test article extract must be non-hemolytic. | Non-hemolytic |
| **Hemocompatibility -** ISO 10993-4 Unactivated Partial Thromboplastin Time Test | The UPTT of the plasma exposed to test article extract should not significantly decreased when compared to untreated and negative controls. | Not an activator |
| **Hemocompatibility -** ISO 10993-4 Complement Activation Assay (SC5b-9) | The plasma exposed to test article must exhibit no significant increase in SC5b-9 when compared to activated NHS and negative control after 60 minutes exposure. | Not an Activator |
| **Hemocompatibility -** ISO 10993-4 Thrombogenicity Study in Dogs | Compare results of test article to predicate control for Thrombogenici response. Determine acceptability of results as part of risk management. | Comparable thromboresistance with control |

**CONCLUSION:**
The CROSSLEAD has similar 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 device. Performance data demonstrates that the device functions as intended.

Therefore, the CROSSLEAD is substantially equivalent to the predicate device.