



July 20, 2023

ASAHI INTECC Co., Ltd.
Cynthia Valenzuela
Director, Regulatory Affairs
3002 Dow Avenue, Suite 212
Tustin, California 92780

Re: K230377

Trade/Device Name: CROSSLEAD Penetration Peripheral Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: July 3, 2023
Received: July 3, 2023

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,

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

Indications for Use

510(k) Number (if known)

K230377

Device Name

CROSSLEAD Penetration 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.

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510(k) Summary

[as required by 21CFR § 807.92(c)]



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CROSSLEAD Penetration Peripheral Guide Wire

510(k) K230377

DATE PREPARED:	16FEB2023
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TRADE NAME:	CROSSLEAD Penetration Peripheral Guide Wire
DEVICE CLASSIFICATION:	Class II, 21CFR § 870.1330
CLASSIFICATION NAME:	Catheter Guide Wire
PRODUCT CODE:	DQX
PREDICATE DEVICE(S):	ASAHI Peripheral Guide Wire ASAHI Astato XS 40 (K153443)
REFERENCE DEVICE(S):	ASAHI Peripheral Guide Wire ASAHI Halberd (K150445) CROSSLEAD Peripheral Guide Wire (K213315)

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 Penetration Peripheral Guide Wire (hereafter “CROSSLEAD Penetration”) is steerable guide wire with a maximum diameter of 0.014” (0.36 mm) and 0.018” (0.46 mm) and available in 200 cm, 235 cm and 300 cm length. The guide wire is constructed from a stainless steel core wire with a Pt-Ni-Au alloy coil. The coil is soldered to the core wire with Au-Sn solder. The coil has radio - detectability to achieve visibility and can be made to bend 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 Penetration are similar to that previously described in the predicate ASAHI Peripheral Guide Wire ASAHI Astato XS 40 (K153443) (hereafter “ASAHI Astato XS 40”) and reference CROSSLEAD Peripheral Guide Wire (K213315) (hereafter “CROSSLEAD”).and ASAHI Peripheral Guide Wire ASAHI Halberd (K150445) (hereafter “ASAHI Halberd”).

Accessory

There are no accessories packed with CORSSLEAD Penetration.

Comparison with Predicate Device and Reference Device:

Predicate	Device Name	510(K) Number
Primary Predicate	ASAHI Astato XS 40	K153443
Reference Device	CROSSLEAD	K213315
Reference Device	ASAHI Halberd	K150445

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 Penetration	ASAHI Astato XS 40	CROSSLEAD	ASAHI Halberd
	Subject	Predicate	Reference	Reference
510(k)	TBD	K153443	K213315	K150445
Manufacturer	ASAHI INTECC	ASAHI INTECC	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.	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.	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 (Maximum)	0.36 mm (0.014") 0.46 mm (0.018")	0.36 mm (0.014")	0.89 mm (0.035")	0.36 mm (0.014") 0.45 mm (0.018")
Overall Length	200 cm, 235 cm, 300 cm	200 cm, 300 cm	200 cm, 300 cm	200 cm, 235 cm, 300 cm
Coil	Pt-Ni-Au	Pt-Ni	SUS	Pt-Ni
Core Wire	SUS	SUS	Ni-Ti alloy	SUS
Solder	Au-Sn	Ag-Sn Au-Sn	Ag-Sn Au-Sn	Ag-Sn
Tip Shape	Straight, Pre-shape	Straight	Straight, Angled	Straight, Pre-shape
Coating	<Distal> Hydrophilic <Proximal> Hydrophobic	<Distal> Hydrophilic <Proximal> Hydrophobic	<Distal> Hydrophilic <Proximal> Hydrophobic	<Distal> Hydrophilic <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 Penetration 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 Integrity
- Catheter Compatibility
- Appearance and Cleanliness
- Corrosion Resistance
- Kink Resistance
- Radio - detectability
- Dimensional Verification
- Coating Integrity/Particulate Evaluation in a clinically relevant mode

The in vitro bench tests demonstrated that the CROSSLEAD Penetration 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 Penetration 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-sensitizer
Irritation - ISO 10993-23 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.	Non-toxic
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 Thrombogenic response. Determine acceptability of results as part of risk management.	Thromboresistant

CONCLUSION:

The CROSSLEAD Penetration 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 Penetration is substantially equivalent to the predicate device.