December 8, 2021

Asahi Intecc Co., Ltd.
Cynthia Valenzuela
Director, Regulatory Affair
3002 Dow Avenue, Suite 212
Tustin, California 92780

Re: K211898
Trade/Device Name: ASAHI PCI Guide Wire ASAHI CONFIANZA PRO 8-20
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: November 11, 2021
Received: November 23, 2021

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)*

K211898

Device Name

ASAHI PCI Guidewire ASAHI CONFIANZA PRO 8-20

Indications for Use *(Describe)*

PCI Guide Wires are intended to facilitate the placement of balloon dilatation catheters during percutaneous coronary intervention (PCI) and percutaneous transluminal angioplasty (PTA), including use in crossing or assisting in crossing de novo coronary chronic total occlusions (CTO).

The PCI Guide Wires are not to be used in the neurovasculature.

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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ASAHI PCI Guide Wire ASAHI CONFIANZA PRO 8-20

510(K) K211898

DATE PREPARED:	27OCT2021
APPLICANT:	ASAHI INTECC CO., LTD. 3-100 Akatsuki-cho, Seto Aichi 489-0071, Japan
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ALTERNATE CONTACT:	Mr. Hiroshi Obara Manager, Regulatory Affairs ASAHI INTECC CO., LTD. 3-100 Akatsuki-cho Seto, Aichi, Japan 489-0071 Email: hiroshi.obara@asahi-intecc.com
TRADE NAME:	ASAHI PCI Guide Wire ASAHI CONFIANZA PRO 8-20
DEVICE CLASSIFICATION:	Class II, 21CFR § 870.1330
CLASSIFICATION NAME:	Catheter Guide Wire
PRODUCT CODE:	DQX - Wire, Guide, Catheter
PREDICATE DEVICE(S):	ASAHI PTCA Guide Wire ASAHI CONFIANZA PRO 12 (K171933)
REFERENCE DEVICE(S):	ASAHI PTCA Guide Wire ASAHI Gaia Next (K192599) ASAHI Neurovascular Guide Wire ASAHI CHIKAI black (K141751) ASAHI CONFIANZA PRO 12 (K052339)

Intended Use/Indications for Use:

PCI Guide Wires are intended to facilitate the placement of balloon dilatation catheters during percutaneous coronary intervention (PCI) and percutaneous transluminal angioplasty (PTA), including use in crossing or assisting in crossing de novo coronary chronic total occlusions (CTO).

The PCI Guide Wires are not to be used in the neurovasculature.

Description:
The ASAHI PCI Guide Wire ASAHI CONFIANZA PRO 8-20 (Hereafter "ASAHI CONFIANZA PRO 8-20") is a steerable guide wire with a maximum diameter of 0.014 inches (0.36mm) and available in 190cm, 235cm and 300cm length. The extension wire is connected to the end of the guide wire outside the body for 190cm and 235cm wire. The guide wire is constructed from a stainless-steel core wire with a platinum-nickel coil. The coil is soldered to the core wire. 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.

Comparison with Predicate Device:

Predicate Device:

ASAHI PTCA Guide Wire ASAHI CONFIANZA PRO 12 (K171933)

Comparisons of the ASAHI CONFIANZA PRO 8-20 and predicate devices show that the technological characteristics of the ASAHI CONFIANZA PRO 8-20 such as components, design, materials, sterilization method, shelf life and operating principle are identical or similar to the currently marketed predicate device. A tabular comparison of the specific technological characteristics between the predicate device and subject device is provided below.

Name of Device	ASAHI PCI Guide Wire ASAHI CONFIANZA PRO 8-20	ASAHI PTCA Guide Wire ASAHI CONFIANZA PRO 12
510(K)	--	K171933
Intended Use and Indications	PCI Guide Wires are intended to facilitate the placement of balloon dilatation catheters during percutaneous coronary intervention (PCI) and percutaneous transluminal angioplasty (PTA), including use in crossing or assisting in crossing de novo coronary chronic total occlusions (CTO). The PCI Guide Wires are not to be used 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.
Sterilization	Ethylene Oxide to SAL 10^{-6}	
Shelf Life	3 Years	3 Years
Target Body Location	Coronary, Peripheral	
Outer Coil Material	Platinum Nickel	Platinum Nickel
Core Wire Material	Stainless Steel	Stainless Steel
Distal Tip Shape	Straight, Pre-shape	Straight
Overall Length	190cm, 235cm, 300cm	180cm, 300cm
Distal Section Coating length	17cm	20cm
Outside Diameter of Wire	Distal 0.20mm/Proximal 0.36mm	Distal 0.23mm/Proximal 0.36mm

Non Clinical Testing / Performance Data:
The substantial equivalence of the ASAHI CONFIANZA PRO 8-20 line extension 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
- Visual Inspection
- Corrosion Resistance
- Kink Resistance
- Radio - detectability
- Dimensional Verification
- Coating Integrity/Particulate

The in vitro bench tests demonstrated that the ASAHI CONFIANZA PRO 8-20 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 ASAHI CONFIANZA PRO 8-20 was compared to the predicate devices. Based on similarities of the materials used in the subject device to its predicates / reference devices, the biocompatibility of the ASAHI CONFIANZA PRO 8-20 was verified to be the same as those of the predicates / reference devices.

CONCLUSION:
The ASAHI CONFIANZA PRO 8-20 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 ASAHI CONFIANZA PRO 8-20 is substantially equivalent to the predicate device.