



January 2, 2020

Asahi Intecc Co., Ltd.  
% Cynthia Valenzuela  
Director, Regulatory Affairs  
Asahi Intecc USA, Inc.  
3002 Dow Ave, Suite 212  
Tustin, California 92780

Re: K192599

Trade/Device Name: ASAHI PTCA Guide Wire ASAHI Gaia Next  
Regulation Number: 21 CFR 870.1330  
Regulation Name: Catheter Guide Wire  
Regulatory Class: Class II  
Product Code: DQX  
Dated: November 27, 2019  
Received: December 3, 2019

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lydia Glaw, Ph.D.  
Assistant Director  
DHT2C: Division of Coronary  
and Peripheral Interventional 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)  
K192599

Device Name  
ASAHI PTCA Guidewire ASAHI Gaia Next

Indications for Use (Describe)

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.

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:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"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)]

**ASAHI PTCA Guide Wire ASahi Gaia Next**

**510(K)**     K192599    

<b>DATE PREPARED:</b>	18 NOV 2019
<b>APPLICANT:</b>	ASAHI INTECC CO., LTD 3-100 Akatsuki-cho, Seto Aichi 489-0071, Japan
<b>PRIMARY CONTACT:</b>	Mrs. Cynthia Valenzuela Director, Regulatory Affairs ASAHI INTECC USA, INC. 3002 Dow Avenue, Suite 212 Tustin, California 92780 Phone: (714) 442 0575 Fax: (949) 377 3255 Email: <a href="mailto:cynthiav@asahi-intecc-us.com">cynthiav@asahi-intecc-us.com</a>
<b>TRADE NAME:</b>	ASAHI PTCA Guide Wire ASahi Gaia Next
<b>DEVICE CLASSIFICATION:</b>	Class II, 21CFR § 870.1330
<b>CLASSIFICATION NAME:</b>	Catheter Guide Wire
<b>PRODUCT CODE:</b>	DQX - Wire, Guide, Catheter
<b>PREDICATE DEVICE(S):</b>	ASAHI PTCA Guide Wire ASahi Gaia (K171933)
<b>REFERENCE DEVICE(S):</b>	ASAHI PTCA Guide Wire CONFIANZA PRO 12 (K052339) ASAHI PTCA Guide Wire ASahi SION blue (K122468) ASAHI PTCA Guide Wire ASahi Gaia (K138653) ASAHI Neurovascular Guide Wire ASahi CHIKAI black (K141751) ASAHI PTCA Guide Wire ASahi Fielder XT-A (K153106) ASAHI PTCA Guide Wire ASahi SUOH 03 (K162842) ASAHI PTCA Guide Wire ASahi Gladius Mongo (K180784)

**Intended Use/Indications for Use**

*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.*

**Description:**

The ASahi PTCA Guide Wire ASahi Gaia Next (hereafter “ASahi Gaia Next”) is a steerable guide wire with a maximum diameter of 0.014 inches (0.36mm) and available in 190cm length. The extension wire may be connected to the end of the guide wire outside the body. The guide wire is constructed from a stainless-steel core wire with a platinum-nickel and stainless-steel coils. The coil assembly consists of an inner coil and an outer coil, and the coil assembly is soldered to the core wire. The distal end of the guide wire has a radiopaque outer coil and inner coil 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. The coil assembly construction is similar to predicate device.

**Comparison with Predicate Device(s):**

**Predicate Device:**  
ASAHI PTCA Guide Wire ASahi Gaia (K171933)

Comparisons of the ASahi Gaia Next and predicate devices show that the technological characteristics of the ASahi Gaia Next 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.

The main changes from the predicate ASahi Gaia are as follows:

- Outer Coil Material
- Outer Coil Wire
- Inner Coil Material

Name of Device	ASAHI PTCA Guide Wire ASAHI Gaia Next	ASAHI PTCA Guide Wire ASAHI Gaia
510(K)	K192599	K171933
Intended Use and Indications	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 <sup>-6</sup>	
Shelf Life	2 Years	3 Years
Target Body Location	Coronary, Peripheral	
Outer Coil Material	Stainless Steel Platinum Nickel	Platinum Nickel
Outer Coil Wire	7-wire woven coil	Single wire coil
Core Wire Material	Stainless Steel	Stainless Steel
Inner Coil Material	Stainless Steel Platinum Nickel	Stainless Steel
Distal Tip Shape	Pre-shape	Straight, Pre-shape
Overall Length	190cm	190cm, 300cm
Distal Section Coating length	40cm	40cm
Outside Diameter of Wire	ASAHI Gaia Next 1 Distal 0.27mm/Proximal 0.36mm ASAHI Gaia Next 2 Distal 0.30mm/Proximal 0.36mm ASAHI Gaia Next 3 Distal 0.30mm/Proximal 0.36mm	ASAHI Gaia First Distal 0.26mm/Proximal 0.36mm ASAHI Gaia Second Distal 0.28mm/Proximal 0.36mm ASAHI Gaia Third Distal 0.30mm/Proximal 0.36mm

**Non Clinical Testing / Performance Data:**

The substantial equivalence of the ASahi Gaia Next line extension was evaluated in bench testing that followed the recommendations in the FDA draft 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 Gaia Next 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 Gaia Next 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 Gaia Next was verified to be the same as those of the predicates / reference devices. Additional Hemocompatibility testing was conducted due to the change in the coil:

- Hemolysis
- SC5b-9 Complement Activation
- Unactivated Partial Thromboplastin Time
- Thrombogenicity

#### **CONCLUSION:**

The ASAHI Gaia Next has identical 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 Gaia Next is substantially equivalent to the predicate device.