November 21, 2019

Asahi Intecc Co., LTD.
Cynthia Valenzuela
Director, Regulatory Affairs
3002 Dow Ave, Suite 212
Tustin, California 92780

Re: K191464
Trade/Device Name: Asahi PTCA Guide Wire Asahi SION Series
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: September 30, 2019
Received: October 2, 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Lydia Glaw, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191464

Device Name
ASAHI PTCA Guide Wire ASAHI SION Series

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). 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.

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510(K) Summary
[As required by 21CFR§§807.92(c)]

ASAHI PTCA Guide Wire ASAHI

SION Series 510(K): K191464

DATE PREPARED:	05NOV2019
APPLICANT:	ASAHI INTECC CO., LTD. 3-100 Akatsuki-cho, Seto Aichi 489-0071, Japan
PRIMARY CONTACT:	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 Cell Phone: (949) 413 0071 Email: cynthiav@asahi-intecc-us.com
TRADE NAME:	ASAHI PTCA Guide Wires SION Series
DEVICE CLASSIFICATION:	Class II, 21CFR§870.1330
CLASSIFICATION NAME:	Wire, Guide, Catheter
PRODUCT CODE:	DQX, Wire, Guide, Catheter
PREDICATE DEVICE(S):	**Primary Predicate:** ASAHI PTCA Guide Wire ASAHI SION (K100578) ASAHI PTCA Guide Wire ASAHI SION blue (K122468) ASAHI PTCA Guide Wire ASAHI SION J (K122469)

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). The ASAHI PTCA Guide Wires are not to be used in the neurovasculature.

Description:

ASAHI PTCA Guide Wire ASAHI SION (hereafter "ASAHI SION"), ASAHI PTCA Guide Wire ASAHI SION blue (hereafter "ASAHI SION blue") and ASAHI PTCA Guide Wire ASAHI SION J (hereafter "ASAHI SION J") are steerable guidewires with a maximum diameter of 0.014 inches (0.36mm) and available in 180cm, 190cm and 300cm lengths. The guide wire is constructed from stainless-steel core wire with platinum-nickel and stainless-steel coils. The coils assembly consists of an inner coil and an outer coil, as well as a safety wire which is soldered to the inner and outer coils and the core wire. The distal end of the guide wire has a radiopaque tip to achieve visibility and is available in a straight (ASAHI SION) and shaped "J" (ASAHI SION blue, ASAHI SION J) and Pre-Shape (ASAHI SION and ASAHI SION blue) to easily bend with the vessel curve. A hydrophilic coating is applied to the distal portion of the guide wire (ASAHI SION and ASAHI SION J). A silicone and hydrophilic coating are applied to the distal portion of the guide wire for (ASHI SION blue). The proximal sections of the ASAHI SION Series are coated with PTFE.

Comparison with Predicate Device(s):

- ASAHI PTCA Guide Wire ASAHI SION (K100578)
- ASAHI PTCA Guide Wire ASAHI SION blue (K122468)
- ASAHI PTCA Guide Wire ASAHI SION J (K122469)

Comparisons of the ASAHI SION Series and predicate devices show that the technological characteristics of the ASAHI SION Series such as:

- Indications for use
- Fundamental scientific technology
- Fundamental design
- Materials and processes for packaging and sterilization of devices

are similar to the currently marketed predicate devices. A tabular comparison of the specific technological characteristics between the predicate device and subject device is provided below.

Table 1: Comparison table

Name of Device	ASAHI SION	ASAHI SION blue	ASAHI SION J PTCA	SUBJECT DEVICE
510(K) Number:	K100578	K122468	K122469	K191464
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). The ASAHI PTCA Guide wires are not to be used in the neurovasculature.			
Device Description	The ASAHI SION PTCA Guide Wire is a steerable guide wire with a maximum diameter of 0.014 inches (0.36mm) and available in 180cm to 300cm lengths. The extension wire is connected to the end of the guide wire outside the body. The guide wire is constructed from a stainless- steel core wire with platinum-nickel and stainless-steel coils. The coil assembly consists of an inner coil and an outer coil, and there is a safety wire which is soldered to the inner and outer coils and the core wire. The distal end of the guide wire has a radiopaque tip to achieve visibility, and is available in straight configuration 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 proximal section of the guide wire is coated with PTFE.	The ASAHI SION blue PTCA Guide Wire is a steerable guide wire with a maximum diameter of 0.014 inches (0.36mm) and available in 180cm to 300cm lengths. The guide wire is constructed from a stainless steel core wire with platinum -nickel and stainless-steel coils. The coil assembly consists of an inner coil and an outer coil, and there is a safety wire which is soldered to the inner and outer coils and the core wire. The distal end of the guide wire has a radiopaque tip to achieve visibility. The distal end of the coil part is available straight and is made soft to easily bend with the vessel curve, or available in pre-shaped “J”. Silicone and hydrophilic coating are applied to the distal portion of the guide wire. The proximal section of the guide wire is coated with PTFE. The extension wire is connected to the end of the guide wire outside the body for 180cm wire.	The ASAHI SION J PTCA Guide Wire is a steerable guide wire with a maximum diameter of 0.014 inches (0.36mm) and available in 180cm to 300cm lengths. The guide wire is constructed from a stainless steel core wire with platinum-nickel and stainless-steel coils. The coil assembly consists of an inner coil and an outer coil, and there is a safety wire which is soldered to the inner and outer coils and the core wire. The distal end of the guide wire has a radiopaque tip to achieve visibility and is available as a pre-shaped “J”. A hydrophilic coating is applied to the distal portion of the guide wire. The proximal section of the guide wire is coated with PTFE. The extension wire is connected to the end of the guide wire outside the body for 180cm wire.	The ASAHI PTCA Guide Wire ASAHI SION, ASAHI SION blue and the ASAHI SION J are steerable guidewires with a maximum diameter of 0.04 inches (0.36mm) and available in 180cm, 190cm and 300cm lengths. The guide wire is constructed from stainless-steel core wire with platinum-nickel and stainless-steel coils. The coils assembly consists of an inner coil and an outer coil, as well as a safety wire which is soldered to the inner and outer coils and the core wire. The distal end of the guide wire has a radiopaque tip to achieve visibility and is available in a straight (SION) and shaped “J” (SION blue, SION J and Pre-Shape SION and SION blue) to easily bend with the vessel curve. A hydrophilic coating is applied to the distal portion of the guide wire (ASAHI SION and ASAHI SION J). A silicone and hydrophilic coating are applied to the distal portion of the guide wire for (ASHI SION blue). The proximal sections of the SION series are coated with PTFE. The extension wire is connected to the end of the guide wire outside of the body for 180cm and 190cm wires.

Name of Device	ASAHI SION	ASAHI SION blue	ASAHI SION J PTCA
	K100578	K122468	K122469
Regulatory Status:			
Regulation Number:	21 CFR§ 870.1330	21 CFR§ 870.1330	21 CFR§ 870.1330
Regulation Name:	Guide Wire	Guide Wire	Guide Wire
Regulatory Class:	II	II	II
Product Code:	DQX	DQX	DQX
Product Information:			
Core wire	Stainless-steel	Stainless-steel	Stainless-steel
Overall length	180cm & 300cm **Proposed change: Addition of 190cm Model**	180cm & 300cm **Proposed change: Addition of 190cm Model**	180cm & 300cm **Proposed change: Addition of 190cm Model**
Outside diameter of wire	0.014" (0.36mm)	0.014" (0.36mm)	0.014" (0.36mm)
Coil length of radiopaque part	3cm	3cm	3cm
Distal wire coating	Hydrophilic	Hydrophilic and Silicone oil	Hydrophilic
Distal section coating length	285mm	Silicone: 15mm Hydrophilic: 191mm	285mm
Distal end with radiopaque tip	Straight **Proposed addition of: Pre-shape model**	Straight & J-Shape **Proposed addition of: Pre-shape model**	J- Shape **Proposed addition of: 190cm model**
Proximal section coating	PTFE	PTFE **Proposed inclusion: Alternate PTFE coating**	PTFE
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Provided Sterile	Yes	Yes	Yes
Sterility Level	$SAL10^{-6}$	$SAL10^{-6}$	$SAL10^{-6}$
Single Use	Yes	Yes	Yes
Shelf Life	3 Years	3 Years	3 Years

NON CLINICAL TESTING / PERFORMANCE DATA;

Non Clinical laboratory testing was performed on the ASAHI SION Series to determine substantial equivalence. The following testing was performed:

- Tensile Strength
- Torque Strength
- Coat Adhesion
- Particulate

In the *in vitro* bench tests demonstrated that the ASAHI SION Series met all acceptance criteria and performed similarly to the predicate devices. Performance data demonstrates that the device functions as intended, and is substantially equivalent to the predicate devices.

BIOCOMPATIBILITY:

The ASAHI SION Series was tested to assess biocompatibility of the modified coating material.

Table 2: Biocompatibility Summary

Test Method	Standard	Pass / Fail
Cytotoxicity MEM Elution Test – L-929	ISO 10993-5	Pass
Sensitization Kligman Maximization Test - ISO	ISO 10993-10	Pass
Irritation Intracutaneous Injection Test - ISO	ISO 10993-10	Pass
Systemic Toxicity Rabbit Pyrogen Test (material mediated)	ISO 10993-11	Pass
Systemic Toxicity (MHLW) Systemic Injection	SO 10993-11 and MHLW Notice Assessment of Medical Devices #36	Pass
Hemocompatibility Hemolysis	ISO 10993-4	Pass
Hemocompatibility Unactivated Partial Thromboplastin Time Assay (UPTT)	ISO 10993-4	Pass
Hemocompatibility Complement Activation Assay (Direct)	ISO 10993-4	Pass
Hemocompatibility Thrombogenicity	ISO 10993-4	Pass

CONCLUSION:
The ASAHI PTCA Guide Wire ASAHI SION Series has identical intended use, the same similar technological characteristics such as components, design, materials, sterilization method, shelf life and operating principles as the predicate devices. Performance data demonstrates that the device functions as intended.

Therefore, the ASAHI PTCA Guide Wire ASAHI SION Series is substantially equivalent to the predicate devices.