April 2, 2025

Asahi Intecc Co., Ltd.
Cynthia Valenzuela
Director, Quality Systems, Regulatory Affairs/Compliance
Asahi Intecc Usa, Inc.
3002 Dow Avenue
Suite 212
Tustin, California 92780

Re: K243733
Trade/Device Name: SION blue PLUS
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: December 24, 2024
Received: March 3, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Jenny R. Katsnelson -S

Digitally signed by Jenny R. Katsnelson -S
Date: 2025.04.02 17:29:39 -04'00'

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)*
K243733

Device Name
SION blue PLUS

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). 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
(as required by 21 CFR § 807.92)

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SION blue PLUS

510(k) K243733

Date Prepared	03 DEC 2024
Applicant	ASAHI INTECC CO., LTD. 3-100 Akatsuki-cho, Seto, Aichi 489-0071 Japan
Contact	C. Cynthia Valenzuela Director, Quality and Regulatory Affairs ASAHI INTECC USA, Inc. 3002 Dow Avenue, Suite 212 Tustin, CA 92780 Office: (714) 442 0575 Mobile: (949) 745-1617 e-mail: cynthiav@asahi-intecc-us-.com
Trade/Device Name	SION blue PLUS
Device Classification	Class II 21 CFR § 870.1330
Classification Name	Catheter, Guide, Wire
Product Code	DQX – Catheter Guide Wire
Predicate Device	ASAHI PTCA Guide Wire ASAHI SION blue * (K122468, K163426, K191464)
Reference Device	MINAMO blue; MINAMO viola ** (K240387)

*Referred to as SION blue
** Referred to as MINAMO blue/viola

INDICATIONS FOR USE

The indications and Intended Use of SION blue PLUS is as follows:

PCI Guide Wires are intended to facilitate the placement of balloon dilatation catheters during percutaneous coronary intervention (PCI) and percutaneous transluminal angioplasty (PTA).
The PCI Guide Wires are not to be used in the neurovasculature.

DEVICE DESCRIPTION

SION blue PLUS is steerable guide wire with a maximum diameter of 0.36mm (0.014 inches) and available in 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 3cm radiopaque tip to achieve visibility and is available in a straight, Pre-shape and J-shape to bend with the vessel curve. A silicone and hydrophilic coatings are applied to the distal portion of SION blue PLUS. The proximal sections of the SION blue PLUS are coated with PTFE. The extension wire is connected to the end of the guide wire outside of the body for 190cm model.

COMPARISON WITH THE PREDICATE/REFERENCE

A comparison of the SION blue PLUS and the predicate/reference devices shows that the technological characteristics of the subject device such as components, design, materials, sterilization method, shelf life and operating principle are identical or similar to the currently marketed predicate/reference devices.

The table below provides details of similarities between the subject and predicate/reference devices.

The following technological differences exist between the subject and predicate device:

- Exclusion of 180cm length model
- Outer coil length
- Hydrophilic coating length
- PTFE coating length
- All solder of the outer coil is changed to Au-Sn

Table 1: Comparison with predicate/reference devices

Name of Devices	SION blue PLUS	SION blue	MINAMO blue/viola
Device Identifier	Subject	Predicate	Reference
510(k)	TBD	K122468, K163426, K191464	K240387
Manufacturer	ASAHI INTECC	ASAHI INTECC	ASAHI INTECC
Regulation Number	21 CFR§ 870.1330	21 CFR§ 870.1330	21 CFR§ 870.1330
Regulation Name	Catheter, Guide Wire	Catheter, Guide Wire	Catheter, Guide Wire
Regulatory Class	II	II	II
Product Code	DQX	DQX	DQX
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). 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). The ASAHI PTCA Guide Wires are not to be used in the neurovasculature.	PCI Guide Wires are intended to facilitate the placement of balloon dilatation catheter during percutaneous coronary intervention (PCI) and percutaneous transluminal angioplasty (PTA). The PCI Guide Wires are not intended for use in the neurovasculature.
Total Length	190cm, 300cm	180cm, 190cm, 300cm	190cm, 235cm, 300cm
Tip Shape	Straight, Pre-shape, J-shape	Straight, Pre-shape, J-Shape	Straight, Pre-shape, J-shape
Nominal O.D.	0.36mm (0.014”)	0.36mm (0.014”)	0.36mm (0.014”)
Taper Core wire	Austenitic stainless Steel	Austenitic stainless Steel	Austenitic Stainless-Steel Ni-Ti Alloy
Safety Wire	Austenitic stainless Steel	Austenitic stainless Steel	N/A
Inner Coil	Austenitic stainless Steel	Austenitic stainless Steel	Austenitic Stainless-Steel
Outer Coil	Austenitic stainless Steel Pt-Ni Alloy	Austenitic stainless Steel Pt-Ni Alloy	Austenitic Stainless-Steel Pt-Ni Alloy
Solder	Ag-Sn Au-Sn	Ag-Sn Au-Sn	Ag-Sn Au-Sn
Coating	Hydrophilic Silicone PTFE	Hydrophilic Silicone PTFE	Hydrophilic Silicone PTFE PFA
Sterilization	Ethylene oxide SAL 10^{-6}	Ethylene oxide SAL 10^{-6}	Ethylene oxide SAL 10^{-6}

Non-Clinical Bench Testing/Performance Data

The following non-clinical bench testing / performance data for SION blue PLUS provided in support of the substantial equivalence determination. The following testing/assessments were performed:

- Dimensional Verification
- Visual Inspection
- Simulated Use/Human body Phantom
- Tensile Strength (including Tip Pull test)
- Torque Strength
- Torqueability
- Coating Integrity
- Particulate Evaluation
- Lubricity/Catheter Compatibility
- Corrosion Resistance
- Kink Resistance
- Tip Flexibility
- Radiopacity

The *in vitro* bench tests demonstrated the SION blue PLUS met all acceptance criteria and performed similarly to the predicate/reference devices. Performance data demonstrates the device functions as intended and has a safety and effectiveness profile that is similar to the predicate device.

Biocompatibility Testing

To ensure that SION blue PLUS is biocompatible, desk study was conducted leveraging the results of the predicate device; SION blue (K122468, K163426, K191464) and tested articles.

Testing on predicate device and test articles was conducted in accordance with the FDA Guidance "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process'," 08SEP2023, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing within a Risk Management Process," as recognized by FDA. The biocompatibility testing included the following tests:

- Physical and/or chemical information
- Cytotoxicity
- Sensitization
- Irritation / Intracutaneous Reactivity

- Acute systemic Toxicity
- Material-mediated pyrogenicity
- Hemocompatibility
- in vivo thrombogenicity testing

Conclusion

The SION blue PLUS has the same intended use and the same or similar technological characteristics such as components, design, materials, sterilization method and operating principles as the predicate/reference devices. Performance data demonstrates that the device functions as intended.

Therefore, the SION blue PLUS is substantially equivalent to the predicate SION blue (K122468, K163426, K191464).