June 21, 2024

Asahi Intecc Co., Ltd
% C. Cynthia Valenzuela
Director, Quality & Regulatory
Asahi Intecc USA, Inc.
3002 Dow Avenue
Suite 212
Tustin, California 92780

Re: K240387
Trade/Device Name: MINAMO blue; MINAMO viola
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: February 8, 2024
Received: February 8, 2024

Dear C. 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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.

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,

Lydia S. Glaw -S

Digitally signed by Lydia S. Glaw -S
Date: 2024.06.21 10:27:46 -04'00'

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)*
K240387

Device Name
MINAMO blue;
MINAMO viola

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 intended for use 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.

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510(k) Summary

[as required by 21CFR § 807.92(c)]

Global Headquarters and R&D Center
3-100 Akatsuki-cho, Seto-shi, Aichi 489-0071 Japan
TEL : +81-561-48-5551 FAX : +81-561-48-5552
http://www.asahi-intecc.co.jp/

MINAMO blue, MINAMO viola

510(k) K240387

DATE PREPARED:	31 January 2024
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 Email: cynthiav@asahi-intecc-us.com
ALTERNATE CONTACT:	Mr. Hiroshi Obara Manager, Regutatory, Affairs ASAHI INTECC CO., INC. 3-100 Akatsuki-cho Seto, Aichi, Japan 489-0071 Email: hiroshi.obara@asahi-intecc.com
TRADE NAME:	MINAMO blue, MINAMI viola
DEVICE CLASSIFICATION:	Class II, 21CFR § 870.1330
CLASSIFICATION NAME:	Catheter Guide Wire
PRODUCT CODE:	DQX
PREDICATE DEVICE(S):	MINAMO (K190176)
REFERENCE DEVICE(S):	CROSSLEAD Peripheral Guide Wire (K213315) ASAHI PTCA Guide Wire SION blue (K122468, K191464)

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).

The PCI Guide Wires are not intended for use in the neurovasculature.

Description:
The basic structure of the MINAMO blue / viola consists of a hybrid stainless steel and nitinol (Ni-Ti) core wire, with a stainless steel distal inner rope coil. Surrounding the inner rope coil and the distal core wire is a radiopaque platinum nickel / stainless steel outer coil. The outer and inner coils are soldered to the tapered core wire. A similar coil design is used with other ASAHI guide wires, such as the predicate MINAMO (K190176). In addition, coatings are applied on the surface of the product. The coil portion is coated with a silicone and hydrophilic coating. The proximal side of the core wire is coated with PFA, silicone and PTFE.

The nominal outer diameter of the MINAMO is 0.36 mm. The devices are available in three lengths: 190 cm, 235 cm and 300 cm.

The MINAMO blue / viola radiopaque distal tip enables the user to view the position of the tip under X-ray fluoroscopy.

All sizes are available with a straight, pre-shape, and J-shape design.

Accessory
Some model of the MINAMO blue / viola are packaged with a shaping device.
The shaping device can be used to facilitate shaping distal end of the guide wire.

Comparison with Predicate Device and Reference Device:

Predicate	Device Name	510(k) Number
Primary Predicate	MINAMO	K190176
Reference Device	CROSSLEAD Peripheral Guide Wire	K213315
	ASAHI PTCA Guide Wire SION blue	K122468 K191464

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
- Incorporate the same materials

Comparison with Predicate Device and Reference Device

	MINAMO blue MINAMO viola	MINAMO	CROSSLEAD Peripheral Guide Wire	ASAHI PTCA Guide Wire SION blue	Comparison
	Subject	Predicate	Reference	Reference	--
510(k)	TBD	K190176	K213315	K122468, K191464	--
Manufacturer	ASAHI INTECC	ASAHI INTECC	ASAHI INTECC	ASAHI INTECC	--
Regulation Number	21 CFR 830.1330	21 CFR 830.1330	21 CFR 830.1330	21 CFR 830.1330	Same
Regulation Name	Catheter Guide Wire	Catheter Guide Wire	Catheter Guide Wire	Catheter Guide Wire	Same
Regulatory Class	II	II	II	II	Same
Product code	DQX	DQX	DQX	DQX	Same
Indications for Use	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.	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 intended for use in the neurovasculature.	This product is designed to direct a catheter to the desired anatomical location in the peripheral vasculature during diagnostic or interventional procedures.	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.	Same to Predicate

	MINAMO blue MINAMO viola	MINAMO	CROSSLEAD Peripheral Guide Wire	ASAHI PTCA Guide Wire SION blue	Comparison
Nominal Outer Diameter	0.36 mm (0.014 inch)	0.36 mm (0.014 inch)	0.89 mm (0.035 inch)	0.36 mm (0.014 inch)	Same to Predicate
Overall Length	190 cm, 235 cm, 300 cm	190 cm, 300 cm	200 cm, 300 cm	180 cm, 190 cm, 300 cm	Within the range of Predicate
Outer Coil	Pt-Ni Stainless steel	Pt-Ni Stainless steel	Stainless Steel	Pt-Ni Stainless steel	Same to Predicate
Tapered Core Wire	Ni-Ti Stainless steel	Ni-Ti Stainless steel	Ni-Ti	Stainless steel	Same to Predicate
Inner Coil	Stainless steel	Stainless steel	Stainless steel	Stainless steel	Same to Predicate
Tip Shape	Straight, Pre-shape, J-shape	Straight, Pre-shape, J-shape	Straight, Angled	Straight, Pre-shape, J-shape	Same to Predicate
Coating	Hydrophilic Hydrophobic	Hydrophilic Hydrophobic	Hydrophilic Hydrophobic	Hydrophilic Hydrophobic	Same to Predicate or Reference
Solder	Au-Sn Ag-Sn	Ag-Sn	Ag-Sn	Au-Sn Ag-Sn	Same to Predicate or Reference
Pipe joint section structure	Ni-Ti pipe Stainless steel coil	Ni-Ti pipe Stainless steel coil	-	-	Same to Predicate
Sterilization	Ethylene oxide SAL 10^{-6}	Ethylene oxide SAL 10^{-6}	Ethylene oxide SAL 10^{-6}	Ethylene oxide SAL 10^{-6}	Same

The subject MINAMO blue / MINAMO viola has very similar technological characteristics to the predicate, with minor differences in the construction of the distal tip and in the addition of a hydrophobic coating in the mid portion of the guidewire. The biocompatibility and mechanical testing shows the devices to have equivalent performance.

Non Clinical Testing / Performance Data:
The substantial equivalence of the MINAMO blue and MINAMO viola was evaluated in bench testing that followed the recommendations in the FDA guidance document; *Coronary, Peripheral, and Neurovascular Guidewires - Performance Tests and Recommended Labeling*, 10, October 2019.

- Tensile Strength
- Torque Strength
- Torqueability
- Tip Flexibility
- Coating Integrity
- Lubricity
- Visual Inspection
- Corrosion Resistance
- Kink Resistance
- Radiopacity
- Dimensional Verification
- Simulated use in a clinically relevant mode
- Coating Integrity/Particulate Evaluation in a clinically relevant mode

The in vitro bench tests demonstrated that the MINAMO blue and MINAMO viola 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 MINAMO blue and MINAMO viola 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 Partial Thromboplastin Time Test	The PTT 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 Thrombogenici response. Determine acceptability of results as part of risk management.	Thromboresistant

CONCLUSION:
The MINAMO blue and MINAMO viola have 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 MINAMO blue and MINAMO viola are substantially equivalent to the predicate device.