August 1, 2019

Asahi Intecc Co., Ltd.
% Candace Cederman
Principal Consultant
CardioMed Device Consultants, LLC
3168 Braverton Street, Suite 200
Edgewater, Maryland 21037

Re: K190176
Trade/Device Name: Minamo
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: July 2, 2019
Received: July 3, 2019

Dear Candace Cederman:

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 Kenneth Cavanaugh, Ph.D.
Director (Acting)
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

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)*
K190176

Device Name
MINAMO

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 21 CFR 807.92)

3-100 Akatsuki-cho, Seto, Aichi 489-0071 Japan
Tel. +81-561-48-5551 Fax. +81-561-48-5552
Branch office: Tokyo, Nagoya, Osaka, Hong Kong, EU, Singapore, Beijing, India, Middle Eastern
Research Facilities and Factories: Osaka, Seto, Thailand, Hanoi

MINAMO®

510(k) K190176

Date Prepared:	27 June 2019
Applicant:	ASAHI INTECC CO., LTD. 3-100 Akatsuki-cho, Seto, Aichi 489-0071 Japan
Contact:	Yoshi Terai President/CEO ASAHI INTECC USA, Inc. 3002 Dow Avenue, Suite 212 Tustin, CA 92780 Tel: (949) 756-8252, FAX: (949) 756-8165 e-mail: ASAHI.ra-fda@ASAHI-intecc.com
Trade Name:	MINAMO®
Device Classification:	Class 2 per 21 CFR §870.1330
Classification Name:	Catheter, Guide, Wire
Product Code:	DX – Catheter Guide Wire
Predicate Devices:	ASAHI SION blue PTCA Guidewire, K122468
Reference Devices:	Terumo Runthrough NS, K063695 Abbott Balance Middleweight (BMW), K021228

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.

DEVICE DESCRIPTION:

The MINAMO consists of a hybrid NiTi and stainless-steel core wire and a coil assembly on the distal end of the device. The coil assembly is soldered to the NiTi portion of the core. In addition, coatings are applied on the surface of the MINAMO. The proximal portion is coated with PTFE. The distal section is coated with hydrophilic coating, with the distal tip coated with silicone. The MINAMO is available in both 190cm and 300cm lengths and with different tip shapes.

COMPARISON WITH PREDICATE DEVICES:

Comparisons of the MINAMO® and predicate / reference devices show that the technological characteristics of the subject device such as the components, design, materials, sterilization method, shelf life and operating principle are similar to the currently marketed predicate and reference devices. The intended use of the subject device and its predicates are the same.

Name of Devices	**MINAMO**	**ASAHI SION blue**	**Runthrough NS**	**BMW**
	Subject	Predicate	Reference	Reference
510(k)	This submission	K122468	K063695	K021228
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 intended for use 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 intended for use in the cerebral blood vessels.	The Runthrough NS are used to facilitate placement of balloon dilatation catheters for percutaneous transluminal coronary angioplasty (PTCA and/or percutaneous transluminal angioplasty (PTA).	To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA) and compatible stent devices during therapeutic intravascular procedures.
Nominal OD	0.36mm (0.014in)	0.36mm (0.014in)	0.36mm (0.014in)	0.36mm (0.014in)
Overall Length	190, 300cm	180, 300cm	180, 300cm	190, 300cm
Outer Coil	Platinum-Nickel and Stainless Steel	Platinum-Nickel and Stainless Steel	Platinum-Nickel and Stainless Steel	Platinum-Nickel and Stainless Steel
Tapered Core Wire	Nitinol and Stainless Steel	Stainless Steel	Nitinol and Stainless Steel	Nitinol and Stainless Steel
Inner Structure	Stainless Steel Coil	Stainless Steel Coil	NA	SUS Shaping Ribbon
Tip Shape	Straight Preshape J-tip	Straight J-tip	Straight	Straight, J-tip
Coating	Hydrophilic Hydrophobic	Hydrophilic Hydrophobic	Hydrophilic Hydrophobic	Hydrophilic Hydrophobic
Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide

NON-CLINICAL TESTING/PERFORMANCE DATA:

Non-clinical laboratory testing was performed on the MINAMO® to determine substantial equivalence. The following testing/assessments were performed:

Non-clinical laboratory testing was performed on the MINAMO to determine substantial equivalence. The following testing/assessments were performed:

- Dimensional verification / Appearance
- Tensile Strength
- Torque Strength
- Torqueability
- Tip Flexibility
- Coating Adhesion
- Catheter Compatibility
- Lubricity
- Corrosion Resistance
- Kink
- Radiodetectability
- Coating Integrity / Acute Particulate Characterization
- Packaging / Transportation assessment

The *in vitro* bench tests demonstrated that the MINAMO 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 devices.

BIOCOMPATIBILITY:

Testing was performed to assess biocompatibility of the modified coating material. The following tests were performed:

- Cytotoxicity
- Sensitization
- Intracutaneous Irritation
- Systemic Toxicity
- USP Rabbit Pyrogen, Material Mediated
- Hemolysis
- Partial Thromboplastin Time
- In Vivo Thromboresistance
- Sc5b-9 Complement Activation

CONCLUSION:

The MINAMO has the same 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 devices. Performance data demonstrates that the device functions as intended.

Therefore, the MINAMO is substantially equivalent to the predicate devices.