Asahi Intecc Co., Ltd.
％Ms. Candace Cederman
CardioMed Device Consultants, LLC
5523 Research Park Drive, Suite 205
Baltimore, MD 21228

Re: K161584
   Trade/Device Name: ASAHI Peripheral Vascular Guide Wire ASAHI Meister 16
   Regulation Number: 21 CFR 870.1330
   Regulation Name: Catheter Guide wire
   Regulatory Class: Class II
   Product Code: DQX
   Dated: September 8, 2016
   Received: September 9, 2016

Dear Ms. 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. 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); good manufacturing practice requirements as set
forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Brian D. Pullin -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

ASAHI Peripheral Vascular Guide Wire is intended for use in the peripheral vasculature, to facilitate the exchange and placement of diagnostic and therapeutic devices such as vascular catheters during peripheral interventional procedures. This guide wire is not intended for use in coronary arteries, lower limb blood vessels, neurovasculature and carotid arteries.

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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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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"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."
Traditional 510(k) Premarket Notification
ASAHI® Peripheral Vascular Guide Wire, ASAHI Meister® 16

ASAHI® Peripheral Vascular Guide Wire ASAHI Meister® 16
510(k) K161584

**DATE PREPARED:** October 4, 2016

**APPLICANT**
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e-mail: ASAHI.ra-fda@ASAHI-intecc.com

**TRADE NAME:** ASAHI® Peripheral Vascular Guide Wire ASAHI Meister® 16

**DEVICE CLASSIFICATION:**
Class 2 per 21 CFR §870.1330

**CLASSIFICATION NAME:** Catheter, Guide, Wire

**PRODUCT CODE**
DQX- Catheter Guide Wire

**PREDICATE DEVICES:**
- ASAHI® Peripheral Vascular Guide Wire: ASAHI® CHIKAI® V (K113716)

**REFERENCE DEVICES:**
- ASAHI® PTCA Guide Wire: ASAHI Fielder (K052022, K062186)
- ASAHI® PTCA Guide Wire: ASAHI Fielder FC J (K072705)
- ASAHI® Neurovascular Guide Wire: ASAHI® CHIKAI® black 18 (K141751)
- Boston Scientific Fathom™ Steerable Guidewires (K111485)

**INTENDED USE/INDICATIONS FOR USE**
ASAHI® Peripheral Vascular Guide Wire ASAHI Meister® 16

ASAHI Peripheral Vascular Guide Wire is intended for use in the peripheral vasculature, to facilitate the exchange and placement of diagnostic and therapeutic devices such as vascular catheters during peripheral interventional procedures. This guide wire is not intended for use in coronary arteries, lower limb blood vessels, neurovasculature and carotid arteries.
DEVICE DESCRIPTION:

The ASAHI® Peripheral Vascular Guide Wire ASAHI Meister® 16 consists of a core wire and a coil assembly. The coil assembly consists of an inner coil and an outer coil, soldered to the core wire. The distal portion of the coil is radiopaque so as to easily confirm its position under radioscopy. In addition, coatings are applied on the surface of ASAHI® Peripheral Vascular Guide Wire ASAHI Meister® 16. The coil and taper core wire of ASAHI® Peripheral Vascular Guide Wire ASAHI Meister® 16 are coated with polyurethane and coated with a hydrophilic polymer upon the polyurethane coat. The distal portion of ASAHI® Peripheral Vascular Guide Wire ASAHI Meister® 16 is soft in order to easily bend in accordance with the vessel curve. The ASAHI® Peripheral Vascular Guide Wire ASAHI Meister® 16 is available in various lengths and tip shapes. Accessories such as a Torque device, Shaping device and Inserter are included in the packaging of the ASAHI® Peripheral Vascular Guide Wire ASAHI Meister® 16.

COMPARISON WITH PREDICATE DEVICE:

Comparisons of the ASAHI® Peripheral Vascular Guide Wire ASAHI Meister® 16 and predicate device shows that the technological characteristics of the Subject device such as the components, design, materials, sterilization method, shelf life and operating principle are identical or similar to the currently marketed predicate devices.

The intended use of the Subject Device and its primary predicates are identical. The indications are very similar, with the indications for the ASAHI® Peripheral Vascular Guide Wire ASAHI Meister® 16 being a subset of that for the ASAHI CHIKAI V. There are specific design features of the Subject device that are similar to the primary predicate but not identical.

<table>
<thead>
<tr>
<th>Name of Device</th>
<th>ASAHI Peripheral Vascular Guide Wire ASAHI Meister 16</th>
<th>ASAHI CHIKAI V Peripheral Vascular Guide Wire</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use and Indications</td>
<td>ASAHI Peripheral Vascular Guide Wire is intended for use in the peripheral vasculature, to facilitate the exchange and placement of diagnostic and therapeutic devices such as vascular catheters during peripheral interventional procedures. This guide wire is not intended for use in coronary arteries, lower limb blood vessels, neurovasculature and carotid arteries.</td>
<td>ASAHI Peripheral Vascular Guide Wire is intended for use in the peripheral vasculature, to facilitate the exchange and placement of diagnostic and therapeutic devices such as vascular catheters during peripheral interventional procedures. This guide wire is not intended for use in neuro- or coronary vasculature.</td>
</tr>
<tr>
<td>Target Body Location</td>
<td>Peripheral</td>
<td></td>
</tr>
<tr>
<td>Overall Lengths</td>
<td>135 cm, 165 cm, and 180 cm</td>
<td>165, 180 cm</td>
</tr>
<tr>
<td>Nominal OD</td>
<td>0.016in</td>
<td>0.014 in</td>
</tr>
<tr>
<td>Outer Coil Material</td>
<td>Platinum-Nickel, Stainless Steel</td>
<td></td>
</tr>
<tr>
<td>Core Wire Material</td>
<td>Stainless Steel</td>
<td></td>
</tr>
<tr>
<td>Hydrophilic coating</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Sterilization</td>
<td>Provided sterile via Ethylene Oxide to SAL106</td>
<td></td>
</tr>
<tr>
<td>Shelf Life</td>
<td>3 Years</td>
<td></td>
</tr>
</tbody>
</table>
NON CLINICAL TESTING / PERFORMANCE DATA:

Non clinical laboratory testing was performed on the ASAHI® Peripheral Vascular Guide Wire ASAHI Meister® 16 to determine substantial equivalence. The following testing/assessments were performed:

- Tensile Strength
- Torque Strength
- Torqueability
- Tip Flexibility
- Coating Adhesion/Integrity
- Catheter Compatibility

The in vitro bench tests demonstrated that the ASAHI® Peripheral Vascular Guide Wire ASAHI Meister® 16 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:

The ASAHI® Peripheral Vascular Guide Wire ASAHI Meister® 16 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® Peripheral Vascular Guide Wire ASAHI Meister® 16 was leveraged from predicates/reference devices for all endpoints other than complement activation.

CONCLUSION:

The ASAHI® Peripheral Vascular Guide Wire ASAHI Meister® 16 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 devices. Performance data demonstrates that the device functions as intended.

Therefore, the ASAHI® Peripheral Vascular Guide Wire ASAHI Meister® 16 is substantially equivalent to the predicate device.