July 18, 2018

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

Re: K180784
Trade/Device Name: ASAHI PTCA Guide Wire ASAHI Gladius Mongo 14, ASAHI Gladius Mongo 14 ES
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: June 20, 2018
Received: June 21, 2018

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. 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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael John -S
2018.07.18 15:29:55 -04'00'

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*

K180784

Device Name

ASAHI® PTCA Guide Wire ASAHI Gladius Mongo 14, ASAHI Gladius Mongo 14 ES

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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51O(k) Summary
[as required by 21 CFR 807.92(c)]

ASAHI® PTCA Guide Wire
ASAHI Gladius Mongo 14 and ASAHI Gladius Mongo 14 ES

510(k) 180784

DATE PREPARED:	July 18, 2018
APPLICANT	ASAHI INTECC CO., LTD. 3-100 Akatsuki-cho Seto, Aichi 489-0071, Japan
CONTACT	Yoshi Terai President/CEO ASAHI INTECC USA, Inc. 2500 Red Hill Avenue, Suite 210 Santa Ana, CA 92705 Tel: (949) 756-8252, FAX: (949) 756-8165 e-mail: ASAHI.ra-fda@ASAH-lintecc.com
TRADE NAME:	ASAHI® PTCA Guide Wire: ASAHI Gladius Mongo 14 and ASAHI Gladius Mongo 14 ES
DEVICE CLASSIFICATION:	Class 2 per 21 CFR §870.1330
CLASSIFICATION NAME:	Catheter, Guide, Wire
PRODUCT CODE	DQX- Catheter Guide Wire
PREDICATE DEVICES:	ASAHI® PTCA Guide Wire • ASAHI® Fielder XT-A (K153106)
REFERENCE DEVICES:	ASAHI® Guide Wire Family (K163426) ASAHI® PTCA Guide Wire • ASAHI SUOH 03 (K162842) • ASAHI RG3 (K141339) • ASAHI Gaia (K133865) • ASAHI SION (K122469) • ASAHI ULTIMATEbros 3 (K101986) • ASAHI Grand Slam (K043422) ASAHI® Chikai Guide Wires (K141751) ASAHI® Peripheral Guide Wire ASAHI Gladius (K150445)

INTENDED USE/INDICATIONS FOR USE
ASAHI® PTCA Guide Wire ASAHI Gladius Mongo 14 (ES)

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® PTCA Guide Wire ASAHI Gladius Mongo consists of a one-piece core wire and a distal 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 the ASAHI® PTCA Guide Wire ASAHI Mongo. The coil and distal portion of the guide wire are coated with polyurethane and then covered with hydrophilic coating. The proximal portion of the guide wire is coated with PTFE only. The ASAHI® PTCA Guide Wire ASAHI Mongo is available in various lengths. The shorter length device is designed for use with a commercially available ASAHI INTECC extension wire.

COMPARISON WITH PREDICATE DEVICE:

Comparisons of the ASAHI® PTCA Guide Wire ASAHI Gladius Mongo and predicate devices show 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 predicates are the same.

Name of Device	**ASAHI® PTCA Guide Wire ASAHI Gladius Mongo 14 and ASAHI Gladius Mongo 14 ES**	**ASAHI® PTCA Guide Wire ASAHI Fielder XT-A**
	Subject	Predicate
510(k)	TBD	K153106
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.	
Target Location	Coronary and Peripheral vasculature	
Nominal OD	0.36mm (0.014 inch)	
Overall Lengths	190cm and 300cm	
Outer Coil Material	ASAHI Gladius Mongo 14: Platinum-Nickel, Stainless Steel ASAHI Gladius Mongo 14 ES: Platinum-Nickel	Platinum-Nickel
Inner Coil Material	Stainless Steel	
Core Wire Material	Stainless Steel	
Undercoating	Polyurethane	
Outer Distal Coating	Hydrophilic coating	
Proximal Coating	PTFE	
Sterilization	Provided sterile via Ethylene Oxide to SAL 10^{-6}	
Shelf Life	3 years	

NON-CLINICAL TESTING/ PERFORMANCE DATA:

Non-clinical laboratory testing was performed on the ASAHI® PTCA Guide Wire ASAHI Gladius Mongo to determine substantial equivalence. The following testing/assessments were performed:

- Tensile Strength
- Torque Strength

- Torqueability
- Tip Flexibility
- Coating Adhesion
- Catheter Compatibility
- Particulate Testing/ Coating Integrity
- Lubricity Testing

The *in vitro* bench tests demonstrated that the ASAHI® PTCA Guide Wire ASAHI Gladius Mongo 14 and ASAHI Gladius Mongo 14 ES met all acceptance criteria and performed similarly to the predicate device. Performance data demonstrate that the devices functions as intended, and have a safety and effectiveness profile that is similar to the predicate devices.

BIOCOMPATIBLIITY:

The ASAHI® PTCA Guide Wire ASAHI Gladius Mongo were compared to the predicate and reference devices. Based on similarities of the materials used in the subject device to its predicates / reference devices, the biocompatibility of the ASAHI® PTCA Guide Wire ASAHI Gladius Mongo **14** and ASAHI Gladius Mongo **14** ES were verified to be the same as those of the predicate *I* reference devices.

CONCLUSION:

The ASAHI® PTCA Guide Wire ASAHI Gladius Mongo have 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® PTCA Guide Wire ASAHI Gladius Mongo **14** and ASAHI Gladius Mongo 14 ES are substantially equivalent to the predicate device.