September 7, 2022

Asahi Intecc Co., LTD.
Cynthia Valenzuela
Director, Regulatory Affairs
3002 Dow Avenue, Suite 212
Tustin, California 92780

Re: K213868
Trade/Device Name: ASAHI Gladius Mongo18 PV ES
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX

Dear Cynthia Valenzuela:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter for your device cleared on September 6, 2022. Specifically, FDA is updating this SE Letter due to the clearance date (September 6, 2022) not appearing on the original letter as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Lydia Glaw, OHT2: Office of Cardiovascular Devices, (301) 796-1456, Lydia.Glaw@fda.hhs.gov.

Sincerely,

Samuel G. Raben -S

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

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Trade/Device Name: ASAHI Gladius Mongo18 PV ES
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: July 6, 2022
Received: July 8, 2022

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 (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,

Samuel G. Raben -S

for Lydia Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
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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)*

K213868

Device Name

ASAHI Gladius Mongo18 PV ES

Indications for Use *(Describe)*

This product is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is intended for peripheral vascular use only.

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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PRAStaff@fda.hhs.gov

"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."

510(K) Summary

[as required by 21CFR § 807.92(c)]

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http://www.asahi-intecc.co.jp/

ASAHI Gladius Mongo18 PV ES

510(K) __K213868_____

DATE PREPARED:	30, August 2022
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: yoshi@asahi-intecc-us.com
TRADE NAME:	ASAHI Gladius Mongo18 PV ES
DEVICE CLASSIFICATION:	Class II, 21CFR § 870.1330
CLASSIFICATION NAME:	Catheter Guide Wire
PRODUCT CODE:	DQX
PREDICATE DEVICE(S):	ASAHI Peripheral Guide Wires (K150445)
REFERENCE DEVICE(S):	ASAHI PTCA Guide Wire FIELDER XT (K072431) ASAHI PTCA Guide Wires, ASAHI Peripheral Guide Wires, ASAHI Guide Wire Extension (K163426) ASAHI PTCA Guide Wire ASAHI Gladius Mongo (K180784)

Intended Use/Indications for Use:

This product is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is intended for peripheral vascular use only.

Description:
The ASAHI Gladius Mongo18 PV ES is a steerable guide wire with a maximum diameter of 0.018 inches (0.45mm) and available in 190cm, 235cm and 300cm length. The distal end of the coil part is available straight and is made soft to easily bend with the vessel curve, or available pre shaped. The guide wire is constructed from a stainless-steel core wire with platinum-nickel coil. The coil is soldered to the core wire. The coil assembly consists of an inner coil and an outer coil, and the coil assembly is soldered to the core wire. The solder of distal end is Au-Sn and other solder is Ag-Sn. The distal end of the guide wire has a radiopaque tip to achieve visibility. For the models covered by this submission, a hydrophilic coating is applied to the guide wire along the distal structure. The proximal section of the guide wire is coated with PTFE. The purpose of these surface coatings is to provide lubricity when guide wire is passed through percutaneous catheters. The basic structure, construction, and coating of the ASAHI Gladius Mongo18 PV ES are unchanged from that previously described in the predicate ASAHI Gladius (K150445).

Accessory
There are no accessories packed with ASAHI Gladius Mongo18 PV ES.

Comparison with Predicate Device and Reference Device:

Predicate	Device Name	510(K) Number
Primary Predicate	ASAHI Gladius	K150445
Reference Device	FIELDER XT	K072431
Reference Device	ASAHI PTCA Guide Wires, ASAHI Peripheral Guide Wires, ASAHI Guide Wire Extension	K163426
Reference Device	ASAHI Gladius Mongo	K180784

The subject device has the following similarities to those which previously received 510(k) clearance.

- Have the same intended use and indications for use
- Use the same operating principle;
- Incorporate the same basic designs; and
- Incorporate the same materials

Comparison with Predicate Device

Name of Devices	**ASAHI Gladius Mongo18 PV ES**	**ASAHI Gladius**
	Subject	Predicate
510(k)	K213868	K150445
Manufacturer	ASAHI INTECC	ASAHI INTECC
Classification Regulation	21 CFR 830.1330, Cardiovascular	
Common Name	Catheter Guide Wire	
Product Code	DQX	
Class	II	
Intended Use	Guide wire for percutaneous intervention	
Indications for Use	This product is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is intended for peripheral vascular use only.	This product is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is intended for peripheral vascular use only.
Nominal OD	0.46mm (0.018inch)	0.36mm (0.014inch) 0.46mm (0.018inch)
Overall Length	190cm, 235cm, 300cm	190cm, 235cm,300cm
Outer Coil	Pt-Ni	Pt-Ni and SUS
Tapered Core Wire	SUS	SUS
Inner Structure	SUS Coil	SUS Coil
Tip Shape	Straight, Pre-shape	Straight, Pre-shape
Coating	<Distal> Hydrophilic <Proximal> Hydrophobic	<Distal> Hydrophilic <Proximal> Hydrophobic
Sterilization	Provided sterile via Ethylene Oxide to SAL 10^{-6}	Provided sterile via Ethylene Oxide to SAL 10^{-6}

Non Clinical Testing / Performance Data:
The substantial equivalence of the ASAHI Gladius Mongo18 PV ES was evaluated in bench testing that followed the recommendations in the FDA guidance document; *Coronary, Peripheral, and Neurovascular Guidewires - Performance Tests and Recommended Labeling*, June 15, 2018.

- Tensile Strength
- Torque Strength
- Torqueability
- Tip Flexibility
- Coating Integrity
- Catheter Compatibility
- Visual Inspection
- Corrosion Resistance
- Kink Resistance
- Radiopacity
- Dimensional Verification
- Particulate

The in vitro bench tests demonstrated that the ASAHI Gladius Mongo18 PV ES met all acceptance criteria and performed similarly to the predicate device. Performance data demonstrate that the device functions as intended and has a safety and effectiveness profile that is similar to the predicate device and the reference device.

BIOCOMPATIBILITY:
The ASAHI Gladius Mongo 18 PV ES was compared to the predicate and reference devices. Based on similarities of the materials used in the subject device to its predicate and reference, the biocompatibility of the ASAHI Gladius Mongo18 PV ES was verified to be the same as those of the predicate and reference devices.

CONCLUSION:
The ASAHI Gladius Mongo18 PV ES has 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 device. Performance data demonstrates that the device functions as intended.

Therefore, the ASAHI Gladius Mongo18 PV ES is substantially equivalent to the predicate device.