DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 9, 2015

Asahi Intecc Co., Ltd.
% Mr. H. Semih Oktay
President
CardioMed Device Consultants, LLC
5523 Research Park Drive, Suite 205
Baltimore, Maryland 21228

Re: K141981
Trade/Device Name: ASAHI FUBUKI 043 and ASAHI FUBUKI Guide Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 5, 2015
Received: February 6, 2015

Dear Mr. Oktay,

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" (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 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 yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141981

Device Name
ASAHI FUBUKI 043 and ASAHI FUBUKI Guide Catheters

Indications for Use *(Describe)*
The ASAHI FUBUKI 043 and ASAHI FUBUKI Guide Catheters are intended to be used to guide interventional devices for neurovascular therapy to a lesion or a procedural site for a percutaneous intravascular procedure in the neurovasculature. This catheter is also intended to be used for injection of contrast media. Do not use this catheter other than 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.

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

ASAHI FUBUKI 043 and ASAHI FUBUKI

510(k) K141981

APPLICANT	Asahi Intecc Co., Ltd. 1703 Wakita-cho, Moriyama-ku Nagoya, Aichi 463-0024 Japan
OFFICIAL CORRESPONDENT	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@asahi-intecc.com
TRADE NAMES:	ASAHI FUBUKI 043 ASAHI FUBUKI
DEVICE CLASSIFICATION:	Class 2 per 21 CFR §870.1250
CLASSIFICATION NAME:	Percutaneous Catheter
PRODUCT CODE	DQY
PREDICATE DEVICES:	K090335, HD Guide Catheter K962362, Envoy Guide Catheter K980453, GUIDER Softip Guiding Catheter
REFERENCE DEVICES:	K083127, Asahi Corsair Microcatheter K132556, SheathLess Eaucath Coronary Guide Catheter K061601, Precious Guide Catheter
DATE PREPARED:	February 5th , 2015

INDICATION FOR USE/INTENDED USE:

ASAHI FUBUKI Intended Use:
This product is intended to be used to guide interventional devices for Neurovascular therapy to a lesion or a procedural site for a percutaneous intravascular procedure in the Neurovasculature. This catheter is also intended to be used for injection of contrast media. Do not use this product other than for use in the Neurovasculature.

ASAHI FUBUKI 043 Intended Use:
This catheter is intended to be used to guide interventional devices for Neurovascular therapy to a lesion or a procedural site for a percutaneous intravascular procedure in the Neurovasculature. This catheter is also intended to be used for injection of contrast media. Do not use this catheter other than for use in the Neurovasculature.

DESCRIPTION:

ASAHI FUBUKI 043 and ASAHI FUBUKI Guide Catheters consists of a guide catheter, available in the following sizes:

Product Name	Outer diameter of Catheter
ASAHI FUBUKI 043	4.2 Fr
ASAHI FUBUKI 6Fr	6 Fr
ASAHI FUBUKI 7Fr	7 Fr
ASAHI FUBUKI 8Fr	8 Fr

The ASAHI FUBUKI Neurovascular Guide Catheter Dilator Kit consists of a Catheter and Dilator components, available in the following sizes:

Product Name	Outer diameter of Catheter	Outer diameter of Dilator Shaft (mm)
ASAHI FUBUKI Dilator Kit 4Fr	6 Fr	1.75
ASAHI FUBUKI Dilator Kit 5Fr	7 Fr	2.00
ASAHI FUBUKI Dilator Kit 6Fr	8 Fr	2.21

The catheter consists of three main sections including a tube, a protector section, and a connector. The proximal part of the tube is covered by the protector and the connector is bonded to the proximal end of the tube. A soft tip is bonded to the distal end of the catheter.

The inner lumen of the tube (excluding the connector portion) is lined with PTFE to facilitate movement of the guide wire and other devices. The tube is made of polymer resin and is reinforced by a stainless steel and tungsten braid wire. The outer surface of the tube is partially coated with a hydrophilic polymer.

COMPARISON TABLE WITH PREDICATE DEVICES:

Comparisons of the ASAHI FUBUKI 043 and ASAHI FUBUKI with the predicate devices show that the technological characteristics of the ASAHI FUBUKI 043 AND ASAHI FUBUKI such as the intended use, components, design, materials, sterilization method, shelf life and operating principle are similar to the currently marketed predicate devices. A comparison of the ASAHI FUBKI 043 and the ASAHI FUBUKI to the predicate devices is provided in the table below.

Device Name / ***Comparison Criteria***	***ASAHI FUBUKI 043***	***ASAHI FUBUKI***	***HD Guide Catheter***	***Envoy***	***GUIDER Softip Guiding Catheter***
Manufacturer	ASAHI INTECC CO., LTD.	ASAHI INTECC CO., LTD.	Concentric	Cordis	Schneider
Indications for Use	This catheter is intended to be used to guide interventional devices for Neurovascular therapy to a lesion or a procedural site for a percutaneous intravascular procedure in the Neurovasculature. This catheter is also intended to be used for injection of contrast media. Do not use this catheter other than for use in the Neurovasculature.	This product is intended to be used to guide interventional devices for Neurovascular therapy to a lesion or a procedural site for a percutaneous intravascular procedure in the Neurovasculature. This catheter is also intended to be used for injection of contrast media. Do not use this product other than for use in the Neurovasculature.	The HD Guide Catheter is indicated for use in facilitating the insertion and guidance of an occlusion catheter, infusion catheter or other appropriate microcatheter into a selected blood vessel in the peripheral, coronary and neurovascular systems. It may also be used as a diagnostic angiographic catheter.	The Envoy Guiding Catheter is intended to use in the peripheral, coronary and neurovasculature for the intravascular introduction of interventional / diagnostic devices.	The SCHNEIDER GUIDER Softip Guiding Catheter are designed for introduction of interventional devices. They are intended to facilitate the placement of interventional devices into the peripheral and coronary systems and, in additional for the XF models, into the neurovascular system.
Labeled Shaft Outer Diameter	4.2 Fr,	6Fr, 7Fr, 8 Fr	3.9Fr - 5.2 Fr	5Fr, 6Fr	5Fr, 6 Fr, 7 Fr, 8 Fr, 9 Fr
Inner Diameter	4.2 Fr : 1.10mm (0.043 in)	6Fr : 1.80mm (0.071 in) 7Fr : 2.05mm (0.081 in) 8Fr : 2.28mm (0.090 in)	Not Provided	5Fr : 1.4mm (0.056 in) 6Fr : 1.8mm (0.070 in)	5 Fr : 1.35mm (0.053 in) 6 Fr : 1.63mm (0.064 in) 7 Fr : 1.85mm (0.073 in) 8 Fr : 2.18 mm (0.086 in) 9 Fr : 2.51mm (0.099 in)
Catheter Effective Length	1200mm – 1300mm	800mm – 1100mm	1150mm – 1360mm	900, 1000mm	900, 1000mm

Device Name / *Comparison Criteria*	*ASAHI FUBUKI 043*	*ASAHI FUBUKI*	*HD Guide Catheter*	*Envoy*	*GUIDER Softip Guiding Catheter*
Tip Shape	Straight	Straight Angled	Unknown	Straight Multipurpose C Multipurpose D Modified Cerebral (Burke) Headhunter 1 Simmons 2	40° Angle Multipurpose Straight
Primary catheter material	Polyurethane Polyamide	Polyurethane Polyamide	Polyamide elastomer	Nylon Polyurethane	Unknown
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide

NON CLINICAL TESTING / PERFORMANCE DATA:

Non clinical laboratory testing was performed on the ASAHI FUBUKI 043 and ASAHI FUBUKI to determine substantial equivalence. The following testing and assessments were performed:

- Corrosion resistance
- Force at break
- Liquid leakage under pressure
- Air leakage into hub assembly during aspiration
- Leak and damage under high static pressure
- Radio-detectability
- Kink resistance
- Appearance/Dimensions

BIOCOMPATIBILITY:

The ASAHI FUBUKI 043 and ASAHI FUBUKI was compared to the predicate devices. Based on similariites of the materials used in the subject devcie to its predicates, the biocompatibiity of the ASAHI FUBUKI 043 and ASAHI FUBUKI was verified to be the same as those of the predicates.

CONCLUSION:

The ASAHI FUBUKI 043 and ASAHI FUBUKI has the same intended use and similar technological characteristics such as components, design, materials, sterilization method, shelf life and operating principles as the predicate devices. Performance data demonstrates that the device functions as intended, and has a safety and effectiveness profile that is similar to the predicate devices.

Therefore, the ASAHI FUBUKI 043 and ASAHI FUBUKI are substantially equivalent to the predicate devices.