October 26, 2022

Filmecc Co. Ltd.
% Candace Cederman
Principal Consultant
CardioMed Device Consultants, LLC
1783 Forest Drive, Suite 254
Annapolis, Maryland 21401

Re: K222631
Trade/Device Name: Vassallo Gt Ext
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: August 30, 2022
Received: August 31, 2022

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 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

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)*
K222631

Device Name
VASSALLO GT EXT

Indications for Use *(Describe)*

The VASSALLO GT EXT guide wire accessory is intended for extension of the working length of an already introduced guide wire when exchanging over-the-wire interventional devices during an angioplasty procedure. 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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510(k) Summary
(as required by 21 CFR 807.92)

FILMECC Extension Wire
VASSALLO® GT EXT

510(k) K222631

Date Prepared:	October 14, 2022
Applicant:	FILMECC CO., LTD. 1703 Wakita-cho, Moriyama-ku Nagoya-shi, Aichi 463-0024 Japan TEL : +81-52-768-1212, FAX : +81-52-768-1222
Contact:	Takahiro Kuroiwa Regulatory Affairs FILMECC CO., LTD. 1703 Wakita-cho, Moriyama-ku Nagoya-shi, Aichi 463-0024 Japan TEL : +81-52-768-1212, FAX : +81-52-768-1222 e-mail: takahiro.kuroiwa@filmecc.com
Trade Name:	VASSALLO GT EXT
Device Classification:	Class 2 per 21 CFR §870.1330
Classification Name:	Catheter, Guide, Wire
Product Code:	DQX – Catheter Guide Wire
Predicate Devices:	ASAHI Guide Wire Extension, K101985

INTENDED USE/INDICATIONS FOR USE:

VASSALLO GT EXT

The VASSALLO GT EXT Guide Wire Extension accessory is intended for extension of the working length of an already introduced guide wire when exchanging over-the-wire interventional devices during an angioplasty procedure. This device is intended for peripheral vascular use only.

DEVICE DESCRIPTION:

The VASSALLO GT EXT Guide Wire Extension accessory is used to elongate the working length of compatible peripheral extendable wires. The stainless-steel guide wire extension has an outer diameter of 0.014” (0.36 mm) and a length of 165 cm. The distal end consists of a pipe shaped nitinol-titanium connection port (extension tube). The straight stainless steel wire surface is coated with PTFE.

The extension wire is intended to connect with a FILMECC peripheral guide wire shorter than 300 cm. The total length of the system after connection will be 300 cm to 400 cm.

COMPARISON WITH PREDICATE DEVICES:

Comparison of the VASSALLO GT EXT and the predicate device show that the technological characteristics of the subject device such as the components, design, materials, sterilization method, shelf life and operating principle are identical to the currently marketed predicate device. The intended use of the subject device and its predicate are the same.

Name of Devices	VASSALLO GT EXT	ASAHI Guide Wire Extension
	Subject	Predicate
510(k)	K222631	K101985
Intended Use and Indications	Intended for extension of the working length of an already introduced guide wire when exchanging over-the-wire interventional devices during an angioplasty procedure This device is intended for peripheral vascular use only.	Intended for extension of the working length of an already introduced guide wire when exchanging over-the-wire interventional devices during an angioplasty procedure
Target location	Peripheral	Coronary and Peripheral
Nominal OD	0.36 mm (0.014 inch)	0.36 mm (0.014 inch)
Overall Length	165 cm	165 cm
Tapered Core Wire	Stainless Steel	Stainless Steel
Extension Tube	Ni-Ti alloy	Ni-Ti alloy
Hydrophobic Coating	PTFE	PTFE
Sterilization	EO	EO
Shelf Life	3 years	3 years

NON-CLINICAL TESTING/PERFORMANCE DATA:

Non-clinical laboratory testing was performed on the VASSALLO GT EXT to determine substantial equivalence. Testing involved evaluating the joint strength of the extension tube and core wire of extension wire in addition to the joint strength of the extension tube and the core extension wire.

The *in vitro* bench tests demonstrated that the VASSALLO GT EXT met all acceptance criteria and that the device functions as intended and has a safety and effectiveness profile that is similar to the predicate device.

CONCLUSION:

The VASSALLO GT EXT accessory 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 device. Performance data demonstrates that the device functions as intended. The conclusion drawn from the nonclinical tests demonstrate that the VASSALLO GT EXT is as safe, as effective, and performs as well as or better than the legally marketed predicate device.

Therefore, the VASSALLO GT EXT is substantially equivalent to the predicate devices.