October 11, 2023

Filmec Co. Ltd.
℅ Meagan Fagan
Principal Consultant
CardioMed Device Conultants, LLC
1783 Forest Drive Suite 254
Annapolis, Maryland 21401

Re: K232578
Trade/Device Name: Vassallo GT 018 G12; Vassallo GT 018 G30
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: August 24, 2023
Received: August 25, 2023

Dear Meagan Fagan:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lydia S. Glaw -S

Digitally signed by Lydia S. Glaw -S
Date: 2023.10.11 15:05:50 -04'00'

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)*

K232578

Device Name

VASSALLO GT 018 G12 and VASSALLO GT 018 G30

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)*

[X] 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)

PERIPHERAL GUIDE WIRES VASSALLO® GT 018 G12 and G30

510(k) _K232578_____

Date Prepared:	August 24, 2023
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:	Noriaki Tsuzuki Regulatory Affairs / Vigilance Section 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: noriaki.tsuzuki@filmecc.com
Trade Name:	VASSALLO® GT
Device Classification:	Class II per 21 CFR §870.1330
Classification Name:	Catheter, Guide, Wire
Product Code:	DQX – Catheter Guide Wire
Predicate Devices:	Filmecc VASSALLO GT (K203533)
Reference Devices	Filmecc VASSALLO GT 018 Floppy (K213949)

INTENDED USE/INDICATIONS FOR USE:

VASSALLO® GT

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

DEVICE DESCRIPTION:

The VASSALLO® GT 018 G12 and G30 Peripheral Guide Wires in this submission are a steerable guide wire with a maximum diameter of 0.018 inches (0.45mm) in available lengths of 190cm and 300cm.

The devices have a solid core with a hydrophilic coated coil-type distal end. The entire coil is radiopaque to facilitate selection of the blood vessel and confirmation of the position of the guide wire's distal end by fluoroscopy.

The core shaft surface is coated with Polytetrafluoroethylene (PTFE). About 2 cm of the distal end can be shaped. A detachable extension wire (hereafter "extension wire") is available to connect with the proximal end of the guide wire with a length of less than 300 cm. A Torque device is included in the same package.

COMPARISON WITH PREDICATE DEVICE:

Comparisons of the VASSALLO® GT 018 G12 and G30 and 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 similar, if not identical, to the currently marketed predicate device. The intended use of the subject devices and its predicate are the same.

Name of Devices	**VASSALLO® GT 018 G12 and G30**	**VASSALLO GT Floppy and G40**	**VASSALLO GT 018 Floppy**
	Subject	Predicate	Reference
510(k)	TBD	K203533	K213949
Intended Use and Indications	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	0.45mm (0.018in)	0.36mm (0.014in)	0.45mm (0.018in)
Overall Length	190, 300cm		
Outer Coil	Platinum-Nickel	Platinum-Nickel or Platinum-Nickel/Stainless Steel	Platinum-Nickel/Stainless Steel
Tapered Core Wire	Stainless Steel		
Tip Shape	Straight (shapeable)		
Coating	Hydrophilic, Hydrophobic		
Sterilization	Ethylene Oxide, SAL 10^{-6}		

NON-CLINICAL TESTING/PERFORMANCE DATA:

Non-clinical laboratory testing was performed on the VASSALLO® GT 018 G12 and G30 to determine substantial equivalence to the predicate device. The following testing/assessments were performed:

- Dimensional Verification
- Visual Inspection
- Tensile Strength / Tip Pull
- Torque Strength
- Torqueability
- Coating Adhesion/Integrity
- Catheter Compatibility / Lubricity
- Corrosion Resistance
- Kink Resistance
- Tip Flexibility
- Radiopacity

The *in vitro* bench tests demonstrated that the VASSALLO GT 018 G12 and G30 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:

Testing was performed to assess biocompatibility of the predicate VASSALLO GT. The following tests were performed:

- Cytotoxicity
- Sensitization
- Intracutaneous Irritation
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemolysis
- Partial Thromboplastin Time
- In Vivo Thromboresistance
- Complement Activation (SC5b-9)

The results from this testing are being leveraged for the subject device and support the biocompatibility of the VASSALLO GT 018 G12 and G30.

STERILIZATION:

The minor dimensional differences of the subject device do not represent a greater sterilization challenge than the predicate VASSALLO GT guide wires. As such, no additional sterilization validation was required, and the subject device was adopted into the product family for which a sterilization cycle was validated in accordance with AAMI TIR28.

CONCLUSION:

The VASSALLO GT 018 G12 and G30 have 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 conclusions drawn from the nonclinical tests demonstrate that the subject VASSALLO GT 018 is as safe, as effective, and performs as well as or better than the legally marketed predicate device.

Therefore, the VASSALLO GT 018 G12 and VASSALLO GT 018 G30 are substantially equivalent to the predicate devices.