April 21, 2021

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

Re: K203533
Trade/Device Name: Vassallo Gt
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: March 26, 2021
Received: March 29, 2021

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K203533

Device Name
VASSALLO® GT Guide Wire

Indications for Use *(Describe)*
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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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**510(k) Summary**
(as required by 21 CFR 807.92)

# PERIPHERAL GUIDE WIRES
# VASSALLO® GT

**510(k) K203533**

| | |
|---|---|
| **Date Prepared:** | 1 December 2020 |
| **Applicant:** | FILMECC CO., LTD.<br>1703 Wakita-cho, Moriyama-ku<br>Nagoya-shi, Aichi 489-0071<br>Japan<br>TEL : +81-52-768-1212, FAX : +81-52-768-1222 |
| **Contact:** | Takahiro Kuroiwa<br>Regulatory Affairs<br>FILMECC CO., LTD.<br>1703 Wakita-cho, Moriyama-ku<br>Nagoya-shi, Aichi 489-0071<br>Japan<br>TEL : +81-52-768-1212, FAX : +81-52-768-1222<br>e-mail: takahiro.kuroiwa@filmecc.com |
| **Trade Name:** | VASSALLO® GT |
| **Device Classification:** | Class 2 per 21 CFR §870.1330 |
| **Classification Name:** | Catheter, Guide, Wire |
| **Product Code:** | DQX – Catheter Guide Wire |
| **Predicate Devices:** | ASAHI Peripheral Guide Wire, K150445 and K163426 |
| **Reference Devices:** | ASAHI Astato XS 40, K153443<br>ASAHI Regalia XS 1.0, K083146<br>ASAHI PROWATER, K022762 and K070945 |

## INTENDED USE/INDICATIONS FOR USE:

VASSALLO® GT
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.

## DEVICE DESCRIPTION:

The VASSALLO® GT Peripheral Guide Wires in this submission are steerable guide wires with a maximum diameter of 0.014 inches (0.36mm) and available in 190cm and 300cm lengths.

These devices have a solid core with a hydrophilic coil-type distal end. When wet, the hydrophilic coating increases the lubricity of the guidewire surface. Some models also include silicone coating on the distal tip. The coil is partly or entirely 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 2cm 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 DEVICES:

Comparisons of the VASSALLO GT® and predicate / reference devices show that the technological characteristics of the subject device such as the components, design, materials, sterilization method, shelf life and operating principle are similar to the currently marketed predicate and reference devices. The intended use of the subject device and its predicates are the same.

| **Name of Devices** | **VASSALLO GT®** | **ASAHI Peripheral Guide Wires ASAHI Gladius, ASAHI Halberd ASAHI Gaia PV** |
|---|---|---|
| | Subject | Primary Predicate |
| 510(k) | TBD | K150445 and K163426 |
| 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. | 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 | 0.36mm (0.014in) | 0.36mm and 0.45mm (0.014in and 0.018in) |
| Overall Length | 190, 300cm | 200cm to 300cm |
| Outer Coil | Platinum or Platinum-Nickel and Stainless Steel | Platinum-Nickel and Stainless Steel |
| Tapered Core Wire | Stainless Steel | Stainless Steel |
| Inner Structure | -- | Stainless Steel Coil |
| Tip Shape | Straight | Straight Preshape |
| Coating | Hydrophilic, Hydrophobic | Hydrophilic, Hydrophobic |
| Sterilization | Ethylene Oxide | Ethylene Oxide |

## NON-CLINICAL TESTING/PERFORMANCE DATA:

Non-clinical laboratory testing was performed on the VASSALLO® GT to determine substantial equivalence. The following testing/assessments were performed:

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

The *in vitro* bench tests demonstrated that the VASSALLO GT met all acceptance criteria and performed similarly to the predicate and reference 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 VASSALLO GT. The following tests were performed:

- Cytotoxicity
- Sensitization
- Intracutaneous Irritation
- Systemic Toxicity
- Pyrogen, Material Mediated
- Hemolysis
- Partial Thromboplastin Time
- In Vivo Thromboresistance
- SC5b-9 Complement Activation

The results from the testing performed showed the VASSALLO GT to be biocompatible.

## CONCLUSION:

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

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