February 22, 2021

Front Line Medical Technologies, Inc.
℅ Sharon Iverson
Quality and Regulatory Director
Covance, Inc.
5353 Wayzata Blvd. Suite 505
Minneapolis, Minnesota 55416

Re: K201652
Trade/Device Name: COBRA-OS Kit, Accessory 4Fr Custom Introducer Sheath Kit, Accessory 10cc Syringe, COBRA-OS occlusion device
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: MJN
Dated: January 15, 2021
Received: January 19, 2021

Dear Sharon Iverson:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. 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 Carmen Gacchina Johnson, PhD
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular 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)*
K201652

Device Name
COBRA-OS™

Indications for Use *(Describe)*
The COBRA-OS™ is intended for temporary occlusion of large vessels including patients requiring emergency control of hemorrhage.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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."

5.0 TRADITIONAL 510(K) SUMMARY

Submitted by:	Front Line Medical Technologies Inc. 609 Wellington St., London, Ontario, N6A3R6 Canada
Contact Person:	Asha Parekh CEO Front Line Medical Technologies Inc. 609 Wellington St. London, Ontario, N6A3R6 Canada Telephone (519) 777-1577 Email asha@frontlinemedtech.com
Date of Summary:	15 JUN 2020
Trade or Proprietary Name:	COBRA-OS™ Kit Reference Number F01K1
Common or Usual Name:	Catheter, Intravascular Occluding, Temporary
Classification Name:	Vascular Clamp
Regulation Number	21 CFR 870.4450
Classification:	Class II
Product Code:	MJN
Review Panel:	Cardiovascular
Predicate Device:	ER-REBOA™, K170411

Device Description: The COBRA-OS™ is a large vessel occlusion device and includes a 4 French Custom Sheath Introducer Kit and a 10 cc syringe.

The occlusion device consists of a stiff inner guidewire with an atraumatic floppy distal J-tip that is housed in a compliant occlusion balloon with proximal and distal necks. The inner guidewire provides adequate stiffness. No other guidewires are required. The proximal neck of the balloon is connected to an overmolded hub and stopcock for balloon inflation and deflation. Suture tabs on the overmolded hub are used to secure the device to the patient's skin with sutures. A J-tip straightener is included and preloaded on the distal neck to facilitate the introduction of the device into the 4 French introducer sheath hemostasis valve. Pad printing marks on the outer occlusion device shaft indicate distance to the desired location.

Intended Use: The COBRA-OS™ is intended for temporary occlusion of large vessels.

Indications for Use: The COBRA-OS™ is intended for temporary occlusion of large vessels including patients requiring emergency control of hemorrhage.

Technological Characteristics:

The subject device has the same intended use, principles of operation, and basic technological characteristics for obtaining occlusion of the vessel.

The COBRA-OS™ has the following main differences from the predicate device:

- Compatible with 4 Fr introducer sheath
- 64.9 cm effective length
- Includes accessories (4 Fr Custom Sheath Introducer Kit and 10 cc syringe)
- Atraumatic distal J-Tip
- Does not monitor blood pressure

The following performance bench and in vivo (animal) testing were performed to support the substantial equivalence of COBRA-OS to the identified predicate.

Performance Data (non-clinical):

- Dimensional
- Balloon Inflation/Deflation
- Balloon Diameter to Inflation Volume
- Balloon Burst
- Maximum Inflation Volume

- Tensile Strength
- Fatigue
- Torque
- Kink Radius
- Freedom From Leakage
- Occlusion Time
- Human Factors/Usability
- Sterilization
- Packaging
- Shelf Life
- Biocompatibility

Performance Testing (animal):

Performance testing was also conducted in vivo (swine model). The COBRA-OS™ meets applicable design and performance requirements.

Substantial Equivalence Conclusion: Based on the intended use, principles of operation, basic technological characteristics for obtaining occlusion of the vessel, and performance testing, the COBRA-OS™ is found substantially equivalent to the legally marketed predicate device.