May 3, 2021

MC3, Inc.
Martha Rumford
VP Regulatory
2555 Bishop Circle West
Dexter, Michigan 48130

Re: K203409
Trade/Device Name: MC3 Crescent™ Jugular Dual Lumen Catheter
Regulation Number: 21 CFR 870.4100
Regulation Name: Extracorporeal Circuit And Accessories For Long-Term Respiratory/Cardiopulmonary Failure
Regulatory Class: Class II
Product Code: PZS
Dated: March 26, 2021
Received: March 29, 2021

Dear Martha Rumford:

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 Nicole Gillette
Assistant Director (Acting)
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)*
K203409

Device Name
MC3 Crescent™ Jugular Dual Lumen Catheter

Indications for Use *(Describe)*
The MC3 Crescent™ Jugular Dual Lumen Catheter is a single use, dual lumen catheter that provides both venous drainage and reinfusion of blood via the jugular vein and is indicated for use in adult and pediatric patients with acute respiratory failure requiring Veno-Venous Extracorporeal Membrane Oxygenation, where other available treatment options have failed and continued clinical deterioration is expected or the risk of death is imminent.

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
MC3 Jugular Dual Lumen Catheter

Date Prepared:	May 3, 2021
Sponsor Information:	
Owner/Applicant/Submitter:	MC3 Incorporated 2555 Bishop Circle West Dexter, MI 48130 1-734-995-9089 Registration number: 3011468686
Contact Person:	Martha Rumford VP Regulatory 2555 Bishop Circle West Dexter, MI 48130 734.995.9089
Device Names/Classification:	
Device Trade Name:	MC3 Crescent™ Jugular Dual Lumen Catheter
Device Common Name:	Dual Lumen ECMO Cannula
Regulation Name:	Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure
Regulation Number:	21 CFR 870.4100
Product Code:	PZS
Predicate Device:	Jugular Dual Lumen Catheter (K180151)
Reference Devices:	Origen Reinforced Dual Lumen Cannula (K113869)
	Avalon Elite Bi-Caval Dual Lumen Catheter (K081820)

Indications for Use:
The MC3 Crescent™ Jugular Dual Lumen Catheter is a single use dual lumen catheter, which provides both venous drainage and reinfusion of blood via the jugular vein, that is indicated for use in adult and pediatric patients with acute respiratory failure requiring Veno-Venous Extracorporeal Membrane Oxygenation where other available treatment options have failed and continued clinical deterioration is expected or the risk of death is imminent.

Indications for use of the dual lumen catheters remains the same as the predicate device.

Device Description:
The MC3 Jugular Dual Lumen Catheters are dual lumen catheters supplied with an introducer to facilitate wire guided placement into the vasculature via percutaneous (Seldinger type) vascular access methods. The introducer is designed to follow a prepositioned standard guide wire (not included) or obturator (blunt end closed tip introducer) when following a surgical placement. The catheter is wire reinforced

for flexibility and kink-resistance and includes depth marks. Both the introducer and catheter are made of radiopaque materials and the catheter also includes tantalum radiopaque markers at the infusion port, proximal and distal drainage holes, and the catheter tip. The catheter body contains an integrated suture site for use during securement. An optional suture collar is provided and can be used for supplemental securement only. A dilator is also included. The dilators are the same diameter of the catheter and are designed to be used for dilation of the vessel. These catheters are provided in a variety of sizes ranging from 13Fr (8.9 cm insertable length) to 32Fr (34 cm insertable length).

Comparison of Technological Characteristics to Predicate Device:

The MC3 Dual Lumen Catheter product line is extended by scaling the design to include additional sizes. An optional blunt tipped introducer (obturator) and assembly stylet are added to the smallest diameter catheters. All materials and methods of manufacture are identical.

Class II Special Controls

The subject MC3 Crescent™ Jugular Dual Lumen Catheter has demonstrated conformance to the Special Controls outlined in 21 CFR 870.4100 in a manner equivalent to the Predicate Device. The following information outlines how we conform. Because this product is a line-extension, a risk assessment determined when previous testing is applicable to the new design. Special Controls met are:

- ***Technological Characteristics:*** Geometry and design parameters are consistent with the devices intended use in extracorporeal life support procedures. The subject device is designed to be compatible with other extracorporeal circuit devices and accessories.

- ***Biocompatibility:*** The subject device is demonstrated to be biocompatible as a prolonged use device in accordance with ISO 10993-1:2009 and GLP (21 CFR 58), and pursuant to FDA guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.'"

- ***Sterility and Shelf-life:*** Testing demonstrates the sterility of the subject device as provided and that it maintains its sterility, integrity, durability, and reliability over the stated Shelf-life of the device.

- ***Non-clinical Performance:*** Substantial equivalence is demonstrated by performance characteristics on the bench, mechanical integrity, 30-day durability, and reliability for a long-term duration of use.

- ***In vivo Evaluation:*** 7-day in vivo thrombogenicity evaluation demonstrates the subject device's performance over a long-term duration of use in a biologic test system.

- ***Labeling:*** The instructions for use includes a detailed summary of the non-clinical and in vivo evaluations pertinent to the device's use in an extracorporeal circuit. Adequate instructions are also included with respect to anticoagulation, circuit setup, maintenance during a procedure, and performance characteristics relevant to compatibility among different devices and accessories in the circuit.

Conclusion: The information and data included in this 510(k) Notification demonstrate that the subject MC3 Crescent™ Jugular Dual Lumen Catheter is substantially equivalent to the Predicate Device for both venous drainage and reinfusion of blood via the jugular vein during extracorporeal life support procedures in patients with acute respiratory or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent.