July 16, 2018

MC3 Incorporated
Adam Viitala
Regulatory Compliance Specialist
2555 Bishop Circle West
Dexter, Michigan 48130

Re: K180151
Trade/Device Name: MC3 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: June 20, 2018
Received: June 21, 2018

Dear Adam Viitala:

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Fernando Aguel -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4 – Indication for Use
MC3 Jugular Dual Lumen Catheter

510(k) Number: K180151

Device Name: MC3 Jugular Dual Lumen Catheter

Indications for Use:

The MC3 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 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.

Prescription Use___X____ or Over-The Counter Use_____

(21 CFR 801 Subsection D) (21 CFR 801 Subsection C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary
MC3 Jugular Dual Lumen Catheter

Date Prepared:	July 12, 2018
Sponsor Information:	
Owner/Applicant/Submitter:	MC3 Incorporated 2555 Bishop Circle West Dexter, MI 48130 1-734-995-9089 Registration number: 3011468686
Contact Person:	Adam W. Viitala Regulatory Compliance Specialist 2555 Bishop Circle West Dexter, MI 48130 734.995.9089, Extension 324
Device Names/Classification:	
Device Trade Name:	MC3 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:	MC3 QuickFlow Dual Lumen Catheter (K171610)
Reference Devices:	Avalon Elite Bicaval Dual Lumen Catheter (K081820)
	Avalon Elite Vascular Access Kit (K081940)

Indications for Use:

The MC3 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 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.

Device Description:

The MC3 Jugular Dual Lumen Catheters are bi-caval dual lumen catheters supplied with an introducer to facilitate wire guided placement into the vasculature via percutaneous surgical methods (Seldinger type approach). The introducer is designed to follow a prepositioned standard 0.038” (0.97 mm) or 0.035” (0.89 mm) guide wire (not included). The introducer hub provides an area for grasping the introducer

during insertion and when fully seated, indicates that the introducer is fully inserted. 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. The catheters remain intact throughout the duration of use and withstand the forces associated with insertion, securement, connection to perfusion line, clamping, blood pressures, and removal. These catheters are provided in the following sizes:

Size	Insertable Length
32Fr	34 cm
30Fr	34 cm
28Fr	34 cm
26Fr	30 cm
24Fr	30 cm

The cannula size and type are chosen by the physician based on the patient's jugular vein size and clinical needs.

BSA (m^2)	Expected cardiac output (C0) l/min (based on 2.5l/min/m^2)	Minimum predicted flow requirements for adequate oxygenation (l/min) (60% of expected CO[1])	Recommended MC3 cannula
≤ 1.6	4	2.4	24, 26, 28, 30, or 32 FR
1.8	4.5	2.7	26, 28, 30, or 32 FR
2.0	5	3	26, 28, 30, or 32 FR
2.2	5.5	3.3	28, 30, or 32 FR

1. Schmidt M et al. Intensive Care Med (2013) 39:838–846; DOI 10.1007/s00134-012-2785-8

In patients on VV ECMO who are hyperdynamic, single access cannulae may not be sufficient to achieve satisfactory support.

Performance Evaluations:

Clinical studies involving patients are not necessary to demonstrate the substantial equivalence of the subject devices. Performance assessments for substantial equivalence were accomplished through bench and in vivo studies that included the following evaluations:

- 30-day Simulated Use Durability Testing
- Pressure/Flow Characteristics
- Kink Resistance Testing
- Tensile Strength Testing
- Leak and Burst Testing
- Introducer Testing
- Hemolysis Testing
- Recirculation Testing
- 7-day In-vivo Testing

Substantial Equivalence Comparison:

Substantial equivalence analysis includes comparison to the Predicate Device with demonstration of conformance to the special controls.

Predicate Device:

A comparison of the MC3 Jugular Dual Lumen Catheter to the Predicate Device shows the following similarities:

- ***Comparison of Intended Use:*** The intended use of both the subject and predicate devices includes veno-venous perfusion during extracorporeal life support procedures.

- ***Comparison of Labeling:*** The labeling that will be used for the MC3 Jugular Dual Lumen Catheter is similar to the labeling used with the Predicate Device. Labeling is designed to provide clarity for the user and satisfy current regulatory requirements. The instructions accurately present the directions necessary for the end-user to employ the device in extracorporeal life support procedures.

- ***Comparison of Operation and Technology:*** The MC3 Jugular Dual Lumen Catheters and the Predicate Device utilize the same general technologies and principles of operation.

- ***Comparison of Design:*** With respect to the design of the MC3 Jugular Dual Lumen Catheters, the main design differences from the Predicate Device include catheter sizes and lengths outside the currently cleared Femoral Dual Lumen Catheters (K171610). These differences have been evaluated on the bench and in in-vivo studies and have been determined to have no adverse impact on performance.

- ***Comparison of Materials:*** The biocompatible materials of construction used in the MC3 Jugular Dual Lumen Catheters are the same type of materials that are used in the Predicate Device.

- ***Comparison of Performance:*** MC3 Incorporated has conducted performance studies with the MC3 Jugular Dual Lumen Catheters to ensure that these devices satisfy appropriate device performance specifications and satisfy user needs. There are no appreciable differences between the subject devices and the Predicate Device.

Special Controls:

The MC3 Jugular Dual Lumen Catheter meets all special controls required by 21 CFR 870.4100 in the same manner as the Predicate Device. 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 MC3 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.