November 16, 2017

MC3 Incorporated
Martha Rumford
Director RA/QA
2555 Bishop Circle West
Dexter, Michigan 48130

Re: K171610
Trade/Device Name: MC3 QuickFlow 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: October 13, 2017
Received: October 16, 2017

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. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Nicole G. Ibrahim -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 QuickFlow™ Dual Lumen Catheter

510(k) Number: K171610

Device Name: MC3 QuickFlow™ Dual Lumen Catheter

Indications for Use:

The MC3 26 Fr. QuickFlow™ Dual Lumen Catheter is a single use dual lumen catheter, which provides both venous drainage and reinfusion of blood via the femoral vein, that is indicated for use for up to 72 hours in patients with acute respiratory failure requiring partial Veno-Venous Extracorporeal Membrane Oxygenation (full hemodynamic support is not required and predicted flows needed to maintain adequate oxygenation do not exceed 3l/min) where other available treatment options have failed and continued clinical deterioration is expected or the risk of death is imminent.

The MC3 28 Fr. QuickFlow™ Dual Lumen Catheter is a single use dual lumen catheter, which provides both venous drainage and reinfusion of blood via the femoral vein, that is indicated for use for up to 72 hours in patients with acute respiratory failure requiring partial Veno-Venous Extracorporeal Membrane Oxygenation (full hemodynamic support is not required and predicted flows needed to maintain adequate oxygenation do not exceed 3.5l/min) 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 QuickFlow Dual Lumen Catheter

Date Prepared: November 16, 2017

Sponsor Information:

Owner/Applicant/Submitter:
MC3 Incorporated
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1-734-995-9089
Registration number: 3011468686

Contact Person:
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Device Names/Classification:

Device Trade Name:	MC3 QuickFlow Dual Lumen Catheter
Device Common Name:	Dual lumen ECMO cannula
Classification Name:	Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure
Regulation Number:	21 CFR 870.4100
Product Code:	PZS

Predicate Device: 81 FR 7451, Feb. 12, 2016

Secondary Predicate Device: Avalon Elite Bi-Caval Dual Lumen Catheter (K081820)

Indications for Use:

The MC3 26 Fr. QuickFlow™ Dual Lumen Catheter is a single use dual lumen catheter, which provides both venous drainage and reinfusion of blood via the femoral vein, that is indicated for use for up to 72 hours in patients with acute respiratory failure requiring partial Veno-Venous Extracorporeal Membrane Oxygenation (full hemodynamic support is not required and predicted flows needed to maintain adequate oxygenation do not exceed 3l/min) where other available treatment options have failed and continued clinical deterioration is expected or the risk of death is imminent.

The MC3 28 Fr. QuickFlow™ Dual Lumen Catheter is a single use dual lumen catheter, which provides both venous drainage and reinfusion of blood via the femoral vein, that is indicated for use for up to 72 hours in patients with acute respiratory failure requiring partial Veno-Venous Extracorporeal

Membrane Oxygenation (full hemodynamic support is not required and predicted flows needed to maintain adequate oxygenation do not exceed 3.5l/min) where other available treatment options have failed and continued clinical deterioration is expected or the risk of death is imminent.

Device Description:

The MC3 QuickFlow Dual Lumen Catheters are dual lumen catheters supplied with an introducer to facilitate wire guided placement into the vasculature by normal access techniques. The introducer is designed to follow a pre-positioned standard 0.038" (0.97 mm) or 0.035" (0.89 mm) guide wire (not included). 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 has radiopaque markers at the tip and most proximal set of drainage holes.

The devices are comprised of two separate thin-walled catheters made of silicone and polyurethane polymer and reinforced with a spring wire. The dual lumen design involves two catheters of different diameters joined together in a co-axial configuration. An arrangement of side holes in the outer (drainage) catheter allows for egress of blood. An open tip on the inner (return) catheter allows for blood ingress. Unreinforced tube extensions with barbed connectors, allowing clamping and connection to the extracorporeal circuit, are joined to the wye junction. A tapered tip introducer is included to facilitate placement of the catheter into the blood vessel over a standard guide wire (not included). Securement of the device may be accomplished via a groove designed in the Y-connector to accept a suture and a suture around a 3/8" barb connector.

The cannula size and type is chosen by the physician based on the patient's femoral vein size and clinical needs, the following table may be used as an aid to choosing the cannula:

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**
$\leq$ 1.6	4	2.4	26 or 28 Fr.
1.8	4.5	2.7	26 or 28 Fr.
2.0	5	3	26 or 28 Fr.
2.2	5.5	3.3	28 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 gas exchange.

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:

- Simulated Use Durability Testing
- Pressure/Flow Characteristics
- Kink Resistance Testing

- Tensile Strength Testing
- Leak and Burst Testing
- Introducer Testing
- Hemolysis Testing
- Recirculation Testing
- In-vivo Testing

Substantial Equivalence Comparison:

Substantial equivalence analysis includes comparison to the special controls of FDA's final order, 81 FR 7451, Feb. 12, 2016, as well as comparison to the Secondary Predicate Device. This is due to the fact that there has been no device yet cleared under regulation 21 CFR 870.4100 to date.

Predicate (Special Controls):

The MC3 QuickFlow Dual Lumen Catheter meets all special controls required by 21 CFR 870.4100. 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 up to 72 hours device in accordance with ISO 10993-1:2009 in accordance with GLP (21 CFR 58).

- ***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, durability, and reliability.

- ***In vivo Evaluation:*** In vivo thrombogenicity evaluation demonstrates the subject device's performance over a 72-hour duration of use.

- ***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. A 72-hour duration of use is specified in the Indication for Use.

Secondary Predicate:

A comparison of the MC3 QuickFlow Dual Lumen Catheter to the Secondary 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 QuickFlow Dual Lumen Catheter is similar to the labeling used with the Secondary 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 QuickFlow Dual Lumen Catheters and the Secondary Predicate Device utilized the same general technologies and principles of operation.

- ***Comparison of Design:*** With respect to the design of the MC3 QuickFlow Dual Lumen Catheters, there are *no significant* design differences from the Secondary Predicate Device. Each of the *non-significant* differences has been determined to have *no* adverse impact on performance.

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

- ***Comparison of Performance:*** MC3 Incorporated has conducted performance studies with the MC3 QuickFlow 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 Secondary Predicate Device.

Conclusion:

The information and data included in this 510(k) Notification demonstrate that the MC3 QuickFlow Dual Lumen Catheter is *substantially equivalent* to the "Predicate Device" for both venous drainage and reinfusion of blood via the femoral vein during extracorporeal life support procedures of up to 72 hours for 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.