October 29, 2018

MC3 Incorporated
% Dave Yungvirt
CEO
Third Party Review Group, LLC
The Old Station House
24 Lackawanna Place
Millburn, New Jersey 07041

Re: K182914
Trade/Device Name: MC3 Vascular Access Kit 21030
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel dilator for percutaneous catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: October 16, 2018
Received: October 18, 2018

Dear Mr. Yungvirt:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Misti L. Malone -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K182914

Device Name
MC3 Vascular Access Kit 21030

Indications for Use *(Describe)*
Intended for single use by a trained physician to assist in vessel cannulation.

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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"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."

510(k) Summary
MC3 Vascular Access Kit

Date Prepared: October 15, 2018

Sponsor Information:

Owner/Applicant/Submitter:
MC3 Incorporated
2555 Bishop Circle West
Dexter, MI 48130
1-734-995-9089
1-734-995-0840 Fax
Registration number: 3011468686

Contact Person:
Adam W. Viitala
Regulatory Affairs Manager
2555 Bishop Circle West
Dexter, MI 48130
734.995.9089, Extension 324

Device Names/Classification:

Device Trade Name:	MC3 Vascular Access Kit 21030
Device Common Name:	Dilator
Classification Name:	Vessel dilator for percutaneous catheterization
Regulation Number:	21 CFR 870.1310
Product Code:	DRE

Predicate Device:

Avalon Elite Vascular Access Kit (K081940)

Indications for Use:

Intended for single use by a trained physician to assist in vessel cannulation.

Device Description:

The MC3 Vascular Access Kit consists of component devices that are already cleared by FDA, as well as various sized dilator devices. The subject devices include dilators that are 13, 16, 20, 24, 26, and 28 French (FR). These dilators are all made of Colorite PVC, 9566M-RAD14. The MC3 logo and size indicator are legibly printed at the hub end of the dilator using NAZDAR VF111 Black Ink with NAZDAR VF190 Ink Thinner.

These dilators are packaged together in the MC3 Vascular Access Kit with other devices already cleared by FDA in accordance with the FDA convenience kit guidance. All kit contents are sterile (EtO), non-pyrogenic, and single use only.

The current FDA cleared devices of the kit include a stainless steel Guidewire; a Stepped Dilator, starting at 8Fr. on the tip transitioning to 10Fr.; a singlewall introducer needle, with protector, that is designed to introduce up to a 0.038" guidewire into the vasculature; a long handle, disposable #11 safety scalpel used for incisions during operational procedures; and a 10ml silicone double seal stopper syringe with luer slip.

Peripheral access to the vein is gained using the needle, syringe, and scalpel. The guidewire is then inserted into the vessel through the needle and the needle is removed. A dilator is then chosen by the physician and inserted over the guidewire into the vessel. The dilator is then removed and the next sized dilator is inserted in the same manner until the desired dilation is achieved. The single-use devices are then disposed after use.

Supporting Data:

Verification and validation testing was used to establish the performance characteristics of the dilators that are provided in the Vascular Access Kit as follows:

- Biocompatibility
- Packaging Integrity
- Transportation Integrity
- Sterilization Validation
- Functional Testing

Comparison to Predicate Device:

A comparison of the subject device to the predicate device, Avalon Elite Vascular Access Kit (K081940), indicates the following similarities:

- Same intended use/indications
- Same operating principle
- Same fundamental technological characteristics
- Same overall design and performance
- Same materials
- Same packaging materials
- Same sterilization requirements
- Similar size range

Summary of Non-clinical Testing:

Test	**Description**	**Results**
Dilator Buckling	Dilator body strength testing with objective acceptance criteria.	All test articles met acceptance criteria. Mechanical integrity is more than adequate for the intended application.
Dilator Tensile Strength	Pull test with objective acceptance criteria.	All test articles met acceptance criteria. Mechanical integrity is more than adequate for the intended application.

Test	Description	Results
Guidewire Fit	0.038" guidewire fits through dilator.	All test articles met acceptance criteria.
Tip Cracking/Kinking	Splitting or cracking testing with objective acceptance criteria.	All test articles met acceptance criteria.
Biocompatibility	Testing per ISO-10993 for an external communicating device in contact with circulating blood for limited duration less than 24 hours.	Under conditions of the study, the dilator materials are not cytotoxic, are not a sensitizer and not an irritant.

Conclusion:

The information and non-clinical data included in the 510(k) Application demonstrate that the MC3 dilators supplied in the MC3 Vascular Access Kit is as safe, as effective, and performs as well as the predicate device; therefore, it is *substantially equivalent* to the predicate device.