DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 1, 2017

Medcomp (Medical Components)
Courtney Nix
Regulatory Affairs Manager, North America and Europe
1499 Delp Drive
Harleysville, Pennsylvania 19438

Re: K162389
Trade/Device Name: Medcomp Vessel Dilator
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel Dilator for Percutaneous Catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: April 20, 2017
Received: April 24, 2017

Dear Courtney Nix:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162389

Device Name
Medcomp Vessel Dilator

Indications for Use *(Describe)*
The Medcomp Vessel Dilators are designed for percutaneous entry into a vessel in order to enlarge the opening of the vessel for the placement of a catheter in a vein or artery.

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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Section 6 — 510(k) Summary

A. **Submitter Information:**

Submitter:	Medcomp® 1499 Delp Drive Harleysville, PA 19438 Tel: (215) 256-4201, x 2285 Fax: (215) 256-9191
Registration Number:	2518902
Contact:	Courtney Nix Cnix@Medcompnet.com Regulatory Affairs Manager: North America and EU
Date Prepared:	08/23/2016

B. **Proposed or Subject Device Information:**

Trade Name:	Medcomp® Vessel Dilator
Common/Usual Name:	Vessel Dilator
Device:	Dilator, Vessel, for Percutaneous Catheterization
Product Code:	DRE
Regulation Description:	Vessel Dilator for percutaneous catheterization
C.F.R. Section:	21 CFR 870.1310
Class:	II
Regulation Medical Specialty and Review Panel:	Cardiovascular

B. **Predicate Device:**

510(k) Number:	K801113
510(k) Holder:	Merit® Medical
Trade Name:	Percutaneous Vessel Dilator
Common/Usual Name:	Dilator

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Device:	Dilator, Vessel for Percutaneous Catheterization
Product Code:	DRE
Regulation Description:	Vessel Dilator for percutaneous catheterization
C.F.R Section:	21 CFR 870.1310
Class:	II
Regulation Medical Specialty and Review Panel:	Cardiovascular

C. **Reference Device Information:**

510(k) Number:	Preamendment Device, Device Listing Number D012540
510(k) Holder:	Cook® Incorporated
Trade Name:	Dilator
Common/Usual Name:	Dilator
Device:	Dilator, Vessel for Percutaneous Catheterization
Product Code:	DRE
Regulation Description:	Vessel Dilator for percutaneous catheterization
C.F.R Section:	21 CFR 870.1310
Class:	II
Regulation Medical Specialty and Review Panel:	Cardiovascular

D. **Purpose for Submission:**

The purpose of this submission is to obtain 510(k) clearance for a new product line for Medcomp®.

E. **Device Description:**

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Medcomp®'s Vessel Dilators are designed for percutaneous entry into a vessel in order to enlarge the opening of the vessel for the placement of a catheter into a vein or artery. The Vessel Dilators range in size from 4F to 24F with lengths of either 15cm (6.0 inches) or 20cm (8.0 inches), are either single or dual taper, and can use guidewire sizes .025", .035", and .038". The Medcomp® Vessel dilators are offered in two different tubing materials (polyethylene or polypropylene) attached to an HDPE hub. Vessel dilators are supplied sterile, for use in an aseptic technique and can only be used once.

G. Indications for Use:

The Medcomp® Vessel Dilators are designed for percutaneous entry into a vessel in order to enlarge the opening of the vessel for the placement of a catheter in a vein or artery.

H. Intended Use:

The Medcomp® Vessel Dilator is intended for use for short term vascular access for percutaneous catheterization.

I. Comparison to Predicate and Reference Devices:

The Medcomp® Vessel Dilator is substantially equivalent to the predicate device, Merit® Medical Percutaneous Vessel Dilator (K801113), and the reference device, Cook® Dilator, preamendment, in terms of indications for use, intended use, specifications, anatomical location, biocompatibility, performance, and labeling.

The difference between the predicate device, Merit® Medical Percutaneous Vessel Dilator (K801113), and the reference device, Cook® Dilator (Preamendment), and the Medcomp® Vessel Dilator is the additional product offering made from polyethylene.

Table 5.1: 510(K) Summary: Design Comparison Matrix

Device	**Medcomp® Vessel Dilator (Proposed)**	**Cook® Dilator Preamendment (Reference)**	**Merit® Medical Percutaneous Vessel Dilator** K801113 **(Predicate)**	**Substantially Equivalent Comparison**
Design	French Size Ranges: 4F-24F Lengths: 15cm, 20cm Guidewire Sizes: .025", .035", .038"	French Size Ranges: 3F-24F Lengths: 10cm, 15cm, 20cm Guidewire Sizes: .018", .025", .035", .038"	French Size Ranges: 4F-6F Lengths: 20cm Guidewire Sizes: .035", .038"	Equivalent

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Indications for Use	The Medcomp vessel dilators are designed for percutaneous entry into a vessel in order to enlarge the opening of the vessel for the placement of a catheter in a vein or artery.	Legally Marketed	The Merit® Medical vessel dilators are designed for percutaneous entry into a vessel utilizing the Seldinger technique in order to enlarge the opening of the vessel for the placement of a catheter in a vein or artery.	Equivalent to Predicate Device
Sterilization	EO	EO	Legally Marketed	Equivalent
Materials	Polyethylene Tube Polypropylene Tube HDPE hubs	Legally Marketed	Polypropylene	Equivalent

J. **Bench / Performance Data / Non-Clinical Testing:**

The results of performance testing, in conjunction with the substantial equivalence claims, effectively demonstrate the proposed device, Medcomp® Vessel Dilator, is equivalent to the reference device, Cook® Dilator, preamendment. The performance testing was performed in accordance with the following standards:

- ISO 11070:2014 – Sterile single-use intravascular introducers, dilators and guidewires
- ISO10555-1 Second edition 2013-07-01, sterile, single-use intravascular catheters - part 1: general requirements. (General Plastic Surgery/General Hospital) (Bench Testing)
- AAMI / ANSI / ISO 10993-1:2009/(R) 2013, biological evaluation of medical devices -- Part 1: evaluation and testing within a risk management process. (Biocompatibility)
- ISO 11135 Second edition 2014, sterilization of health-care products - ethylene oxide - requirements for the development, validation and routine control of a sterilization process for medical devices. (Sterility)
- AAMI / ANSI / ISO 10993-7:2008(R) 2012, biological evaluation of medical devices - part 7: ethylene oxide sterilization residuals. (Sterility)

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- ISO 14971 Second edition 2007-03-01, medical devices - application of risk management to medical devices. (General I (QS/RM))

K. **Biocompatibility:**

Biocompatibility testing was performed on the final, finished, sterile device, Medcomp® Vessel Dilator (proposed) in accordance with ISO 10993-1. The Medcomp® Vessel Dilator (proposed) meets the requirements for limited, less than or equal to 24 hours, contact external communicating device with indirect blood contact. Biocompatibility studies were conducted by a testing facility that is ISO/IEC 17025 certified. GLP studies were conducted in accordance with the U.S. Food and Drug Administration Good Laboratory Practice (GLP) regulations set forth in 21 CFR part 58.

L. **Summary of Substantial Equivalence:**

In conclusion, the Vessel Dilators (proposed device) are substantially equivalent to the predicate (Merit® Medical Percutaneous Vessel Dilator, K801113) and reference device (Cook® Dilator, preamendment). Medcomp®'s Vessel Dilators (proposed device) are substantially equivalent to the reference device (Cook® Dilator, preamendment) in terms of intended use, anatomical location, basic design, performance, and labeling. Medcomp®'s Vessel Dilator (proposed device) are substantially equivalent to the predicate device's (Merit® Medical Percutaneous Vessel Dilator, K801113) instructions for use (labeling).

The proposed device, Vessel Dilators, meets the performance criteria of design verification as specified by ISO standards, guidance documents, and internal test protocols. Through testing, the additional product line made from polyethylene material, the proposed device, Vessel Dilators, are substantially equivalent to the indicated legally marketed reference device (Cook® Dilator, preamendment), and predicate device (Merit® Medical Percutaneous Vessel Dilator, K801113) as defined in the paragraph above.