



May 17, 2018

Medical Components, Inc.
Dba Medcomp®
Courtney Nix
Regulatory Affairs Manager, North America and Europe
1499 Delp Drive
Harleysville, Pennsylvania 19438

Re: K173667
Trade/Device Name: Symetrex™ Long Term Hemodialysis Catheter with Sideholes
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood Access Device and Accessories
Regulatory Class: Class II
Product Code: MSD
Dated: April 12, 2018
Received: April 17, 2018

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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,

Joyce M. Whang -S

for

Benjamin R. Fisher, Ph.D.

Director

Division of Reproductive, Gastro-Renal,
and Urological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K173667

Device Name

Symetrex™ Long Term Hemodialysis Catheter with Sideholes

Indications for Use (Describe)

The Symetrex™ Long Term Hemodialysis Catheter with Sideholes is a symmetric tip dual lumen catheter designed for chronic hemodialysis and apheresis. It may be inserted percutaneously or by cut down. Catheters with greater than 37cm implant length are indicated for femoral placement.

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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Section 6 **510(k) SUMMARY** **Traditional 510K**
K173667

1. Submitter Information:

Submitter: Medical Components Inc.
dba 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: November 27, 2017

2. Proposed or Subject Device Information:

Trade Name: Symetrex™ Long Term Hemodialysis Catheter with Sideholes

Device: Catheter, Hemodialysis, Implanted

Product Code: MSD

Regulation Description: Blood access device and accessories

C.F.R. Section: 21 CFR 876.5540

Class: II

Regulation Medical Specialty and Review Panel: Gastroenterology/Urology

3. Predicate Device Information:

510(k) Number: K171618

510(k) Holder: Medcomp®



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Trade Name:	Symetrex™ Long Term Hemodialysis Catheter
Device:	Catheter, Hemodialysis, Implanted
Product Code:	MSD
Regulation Description:	Blood access device and accessories
C.F.R Section:	21 CFR 876.5540
Class:	II (Special Controls)
Regulation Medical Specialty and Review Panel:	Gastroenterology/Urology

4. Device Description:

The Symetrex™ Long Term Hemodialysis Catheter with Sideholes is a chronic, 15.5 French, dual lumen, radiopaque catheter made of polyurethane. It has a polyester retention cuff and two female luer adapters. The retention cuff promotes tissue ingrowth to anchor the catheter in the subcutaneous tunnel. The luer adapters are identical in color to indicate the reversibility of this catheter. This catheter features symmetrical side channels with a distal tip configuration designed to separate the intake flow from the output flow in both directions.

5. Indications for Use:

The Symetrex™ Long Term Hemodialysis Catheter with Sideholes is a symmetric tip dual lumen catheter designed for chronic hemodialysis and apheresis. It may be inserted percutaneously or by cut down. Catheters with greater than 37cm implant length are indicated for femoral placement.

6. Intended Use:

Long term, greater than 30 days, vascular access for Hemodialysis and Apheresis treatments.

7. Comparison to Predicate Devices:

Symetrex™ Long Term Hemodialysis Catheter with Sideholes is substantially equivalent to the predicate device, Symetrex™ Long Term Hemodialysis Catheter (K171618), in terms of indications for use, labeling, intended use, anatomical location, performance, components, and method of sterilization.

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The difference or changes between the Symetrex™ Long Term Hemodialysis Catheter Sideholes and the predicate, Symetrex™ Long Term Hemodialysis Catheter (K171618) are the sideholes at the distal tip on both the arterial and venous lumen.

Comparison table on the following page.

Table 6.1: 510(K) Summary: Design Comparison Matrix

Device	Proposed Device: Symetrex™ Long Term Hemodialysis Catheter with Sideholes	Predicate Device: Symetrex™ Long Term Hemodialysis Catheter (K171618)
Design	Dual Kidney Shaped Lumen Catheter	Dual Kidney Shape Lumen Catheter
Tip Design	Symmetric Tip, Sideholes at Distal Tip	Symmetric Tip, No Side Holes
Lengths	19cm-42cm	19cm-42cm
Indications for Use	The Symetrex™ Long Term Hemodialysis Catheter with Sideholes is a symmetric tip dual lumen catheter designed for chronic hemodialysis and aphersis. It may be inserted percutaneously of by cut down. Catheters with greater than 37cm implant length are indicated for femoral placement.	The Symetrex™ Long Term Hemodialysis Catheter is a symmetric tip dual lumen catheter designed for chronic hemodialysis and aphersis. It may be inserted percutaneously of by cut down. Catheters with greater than 37cm implant length are indicated for femoral placement.
Catheter O.D.	15.5FR	15.5FR
Sterilization Method	EO Sterilization	EO Sterilization
Materials	Hub (Green): Carbothane w/ 20% BaSO4 Lumen (White): Carbothane w/ 20% BaSO4 Cuff: Polyester Felt	Hub (Green): Carbothane w/ 20% BaSO4 Lumen (White): Carbothane w/ 20% BaSO4 Cuff: Polyester Felt



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	Extension (Clear): Pellethane Barbed Luer (Green) : Isoplast ID Ring (White with red ink): ABS ID Ring (White with blue ink): ABS Clamp (White): Polypropylene	Extension (Clear): Pellethane Barbed Luer (Green) : Isoplast ID Ring (White with red ink): ABS ID Ring (White with blue ink): ABS Clamp (White): Polypropylene																												
Components	Dilator, Stylet, Tunneler, Valved Introducer, and Guidewire	Dilator, Stylet, Tunneler, Valved Introducer, and Guidewire																												
Packaging Systems	Clamshell (Catheters under 33cm): One unit gets a snap lid one unit is sealed into a header bag 5 Header bags are placed in a shipping carton Translumbal tray (Catheters greater than 33cm): One unit gets a snap lid One unit is sealed into a header bag. 5 units are placed into a shipping carton.	Clamshell (Catheters under 33cm): One unit gets a snap lid one unit is sealed into a header bag 5 Header bags are placed in a shipping carton Translumbal tray (Catheters greater than 33cm): One unit gets a snap lid One unit is sealed into a header bag. 5 units are placed into a shipping carton.																												
Performance Testing	Priming Volumes: <table><tr><th>Tip to Cuff Length</th><th>Lumen Volume</th></tr><tr><td>19cm</td><td>2.1cc</td></tr><tr><td>23cm</td><td>2.3cc</td></tr><tr><td>28cm</td><td>2.5cc</td></tr><tr><td>33cm</td><td>2.6cc</td></tr><tr><td>37cm</td><td>2.8cc</td></tr><tr><td>42cm</td><td>3.2cc</td></tr></table> Recirculation:	Tip to Cuff Length	Lumen Volume	19cm	2.1cc	23cm	2.3cc	28cm	2.5cc	33cm	2.6cc	37cm	2.8cc	42cm	3.2cc	Priming Volumes: <table><tr><th>Tip to Cuff Length</th><th>Lumen Volume</th></tr><tr><td>19cm</td><td>2.1cc</td></tr><tr><td>23cm</td><td>2.3cc</td></tr><tr><td>28cm</td><td>2.5cc</td></tr><tr><td>33cm</td><td>2.6cc</td></tr><tr><td>37cm</td><td>2.8cc</td></tr><tr><td>42cm</td><td>3.2cc</td></tr></table> Recirculation:	Tip to Cuff Length	Lumen Volume	19cm	2.1cc	23cm	2.3cc	28cm	2.5cc	33cm	2.6cc	37cm	2.8cc	42cm	3.2cc
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	Symetrex™ Long Term Hemodialysis Catheter with Sideholes has less than 1% recirculation in forward and reverse flow when tested <i>in vitro</i>	Symetrex™ Long Term Hemodialysis Catheter has less than 1% recirculation in forward and reverse flow when tested <i>in vitro</i>
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8. Bench / Performance Data / Non-Clinical Testing:

The results of performance testing, in conjunction with the substantial equivalence claims, effectively demonstrate the proposed device, Symetrex™ Long Term Hemodialysis Catheter with Sideholes, is equivalent to the predicate device, Symetrex™ Long Term Hemodialysis Catheter (K171618). The performance testing was performed in accordance with the following standards:

Table 6.2: Performance Standards

Standard	Standard Title	Revision/ Date	Performance Testing
ISO 10555-1	Intravascular catheters -- sterile and single-use intravascular catheters -- part 1: general requirements.	Second Edition 2013-06-15	Air Leak, Catheter Leak, Extension-Hub, Extrusion-Hub, Gravity Flow
ISO 11607-1	Packaging for terminally sterilized medical devices - part 1: requirements for materials, sterile barrier systems and packaging systems [including: amendment 1 (2014)].	First Edition 2006-04-15	Shipping and Shelf Life testing
ISO 11607-2	Packaging for terminally sterilized medical devices - part 2: validation requirements for	First Edition 2006-04-15	Shipping and Shelf Life testing



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	forming, sealing and assembly processes [including: amendment 1 (2014)].		
ISO 594-1	conical fittings with a 6% (luer) taper for syringes, needles and certain other medical equipment - part 1: general requirements.	First edition 1986-06-15,	Gauging
ISO 594-2	Conical fittings with a 6% (luer) taper for syringes, needles and certain other medical equipment - part 2: lock fittings.	Second Edition 1998-09-01	Liquid Leakage Air Leakage Separation Force Unscrewing Torque Ease of Assembly Resistance to Overriding Stress Cracking

9. Biocompatibility:

Biocompatibility was performed for the Symetrex™ Long Term Hemodialysis Catheter with Sideholes per ISO 10993-1 for a blood implant device with permanent exposure (i.e. > 30 days). Biocompatibility was performed on the final, finished device. The biological end points include:

- Hemocompatibility:
 - ISO 10993-4 *Biological Evaluation Of Medical Devices - Part 4: Selection Of Tests For Interaction With Blood*
 - ASTM F 756-08, *Standard Practice for Assessment of Hemolytic Properties of Materials, 2008*
- Genotoxicity:
 - ISO 10993-3, *Biological Evaluation of Medical Devices - Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity.*
- Cytotoxicity:
 - AAMI / ANSI / ISO 10993-5: *Biological evaluation of medical devices - part 5: tests for in vitro cytotoxicity.*

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- Irritation/Intracutaneous:
 - ISO 10993-10 *Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.*
- Acute Systemic Toxicity:
 - ISO 10993-11 *Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity*
- Implantation:
 - ISO 10993-6 *Biological Evaluation of Medical Devices - Part 6: Tests for Local Effects after Implantation.*
 - ASTM F763-04 *Standard Practice For Short-Term Screening of Implant Materials.*
 - ASTM F981-04 *Standard Practice For Assessment of Compatibility of Biomaterials for Surgical Implants With Respect To Effect of Materials on Muscle and Bone.*
- Additional Testing:
 - ISO 10993-18 *Biological Evaluation of Medical Devices – Part 18: Chemical Characterization of Materials*
 - ASTM D4128-06 *Standard Guide for Identification of Quantitation of Organic Compounds in Water by Combined Gas Chromatography and Electron Impact Mass Spectrometry*
 - ASTM D1971-11 *Standard Practices for Digestion of Water Samples for Determination of Metals by Flame Atomic Absorption, Graphite Furnace Atomic Absorption, Plasma Emission Spectroscopy, or Plasma Mass Spectroscopy*
 - ISO 10993-17 *Biological Evaluation of Medical Devices – Part 17: Establishment of Allowable Limits for Leachable Substances*

10. Summary of Substantial Equivalence:

In conclusion, the proposed device, Symetrex™ Long Term Hemodialysis Catheter with Sideholes, is considered substantially equivalent to the predicate device, Symetrex™ Long Term Hemodialysis (K171618) as demonstrated through non-clinical testing performed.



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