September 14, 2021

Medical Components Inc. (Medcomp®)
Patrick McDonald
Regulatory Affairs Manager, North America and Europe
1499 Delp Drive
Harleysville, Pennsylvania 19438

Re: K210461
Trade/Device Name: End Cap
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: MSD
Dated: August 9, 2021
Received: August 16, 2021

Dear Patrick McDonald:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Glenn B. Bell, Ph.D.
Director
THT3A1: Renal, Gastrointestinal,
Obesity and Transplantation Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K210461

Device Name
End Cap

Indications for Use *(Describe)*
Luer lock plug for capping male or female luer tapers for hemodialysis catheters.

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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medCOMP

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

A. Submitter Information

Submitter Name:	Medical Components Inc. (dba Medcomp®)
Address:	1499 Delp Drive Harleysville, PA 19438 USA Tel (215) 256-4201 Fax (215) 256-9191
Registration Number:	2518902
Contact Person:	Patrick McDonald Senior Regulatory Affairs Manager, North America and EU
Date of Preparation:	06AUG2021

B. Subject Device

Trade Name:	End Cap
Device:	Catheter, Hemodialysis, Implanted
Regulation Description:	Blood access device and accessories
Product Code:	MSD
Regulation Number:	876.5540
Class:	2
Review Panel:	Gastroenterology/Urology

C. Predicate Device

Predicate Trade Name:	The Red Cap
510(k) Number:	K820454
510(k) Applicant:	Burron Medical Products, Inc.
Device:	Syringe, Piston
Regulation Description:	Piston Syringe
Product Code:	FMF
Regulation Number:	880.5860
Class:	II
Review Panel:	General Hospital

D. Device Description:

The Medcomp® End cap is non-vented plastic cap with a male luer. The end cap connects directly to the female luer of the catheter.

E. Indications For Use:

Luer lock plug for capping male or female luer tapers for hemodialysis catheters.

F. Intended Use:

Luer lock plug for capping male or female luer tapers

G. Comparison to Predicate Device:

Table 6.1: 510(k) Summary Design Comparison Matrix

Attribute	Subject Device End Cap	Predicate Device The Red Cap (K820454)
Prescription	Prescription Use	Prescription Use
Intended Use	Luer lock plug for capping male or female luer tapers	Luer lock plug for capping male or female luer tapers
Duration of Use	Short Term Use	Legally Marketed
Sterilization Method	EO	EO

H. Bench/Performance Data/Non-Clinical Testing:

Table 5.2: Applicable Standards and Performance Testing

Standard	Standard Title	Revision/Date	Performance Testing
ISO 594-1:1986	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements	1986	Gauging, Liquid Leakage, Air Leakage, Stress Cracking
ISO 594-2:1998	Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings	1998	Separation Force, Liquid Leakage, Air Leakage, Separation Force, Unscrewing Torque, Ease of Assembly, Resistance to Overriding, Stress Cracking

I. Biocompatibility

The biocompatibility evaluation for the End Cap was conducted in accordance with the FDA guidance document: Use of International

Standard ISO-10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process" and International Standard ISO 10993-1 "Biocompatibility Evaluation of Medical Devices – Part 1 Evaluation and Testing Within a Risk Management Process", as recognized by the FDA. The End Cap met the biocompatibility requirements for an external communicating device with circulating blood contact for a limited (<24 hours) duration. The biological endpoints that were met as are follows:

CYTOTOXICITY

- ISO 10993-5 *Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity*

SENSITIZATION

- ISO 10993-10 *Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization*

IRRITATION OR INTRACUTANEOUS REACTIVITY

- 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*

J. Summary of Substantial Equivalence

Based on the indications for use, design, safety and performance testing, the subject device, End Cap, raises no new questions of effectiveness compared to the predicate device and is substantially equivalent to the predicate device, The Red Cap (K820454).