DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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July 18, 2017

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

Re: K171333
Trade/Device Name: Pro-Lock CT Safety Infusion Set
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: PTI
Dated: July 7, 2017
Received: July 10, 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,

Tara A. Ryan -S

for

Lori Wiggins
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*
K171333

Device Name
Pro-Lock™ CT Safety Infusion Set

Indications for Use *(Describe)*
The Medcomp® Pro-Lock™ CT Safety Infusion Set is intended for use in the administration of fluids and drugs as well as blood sample through implanted vascular access ports. The Medcomp® Pro-Lock™ CT Safety Infusion Set is also indicated for power injection of contrast media into the central venous system with implanted vascular access ports indicated for power injection. The maximum recommended infusion rate at 11.8 cPs is 5ml/sec for 20 gauge non-coring Huber style needles.

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.

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1. **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:	05/05/2017

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

Trade Name:	Pro-Lock™ CT Safety Infusion Set
Device:	Non-Coring (Huber) Needle
Product Code:	PTI
Regulation Description:	Single Lumen Hypodermic Needle
C.F.R. Section:	21 CFR 880.5570
Class:	II
Review Panel:	General Hospital

3. **Predicate Device Information:**

510(k) Number:	K162271
Trade Name:	Pro-Lock™ CT Safety Infusion Set
Device:	Non-Coring (Huber) Needle
Product Code:	PTI
C.F.R. Section:	21 CFR 880.5570

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4. **Device Description:**

The 20G x 5/8" (15mm) Pro-Lock™ CT Safety Infusion Set is composed of a Huber style needle for port septum access having a safety feature designed to prevent accidental needle sticks and automatically activate during needle removal. The needle is connected to a conventional style extension set. The proximal end of the extensions tubing attaches to a female Luer connector with removable cap creating a fluid path to the port. A non-removable pinch clamp is located between the female Luer and needle cannula which is designed to restrict fluid flow through the extension tubing when engaged.

The needle cannula is constructed with a Huber style needle. The cannula is stainless steel and is shielded by a removable star needle guard of plastic construction.

5. **Indications for Use:**

The Medcomp® Pro-Lock™ CT Safety Infusion Set is intended for use in the administration of fluids and drugs as well as blood sampling through implanted vascular access ports. The Medcomp® Pro-Lock™ CT Safety Infusion Set is also indicated for power injection of contrast media into the central venous system with implanted vascular access ports indicated for power injection. The maximum recommended infusion rate at 11.8 cPs is 5 ml/sec for 20 gauge non-coring Huber style needles.

6. **Comparison to Predicate Devices:**

The 20G x 5/8" (15mm) Pro-Lock™ CT Safety Infusion Set is substantially equivalent to the predicate device, 20G x ¾" (19mm) Pro-Lock™ CT Safety Infusion Set (K162271), in terms of indications for use, intended use, materials, biocompatibility, basic design, performance, labeling, patient user inference and manufacturing process.

The difference between the predicate device, 20G x ¾" (19mm) Pro-Lock™ CT Safety Infusion Set (K162271), and the 20G x 5/8" (15 mm) Pro-Lock™ CT Safety Infusion Set is the change in needle length from ¾" to 5/8" and hinge length from 1.164" to 1.114".

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

Device	Proposed Device: 20G x 5/8" (15mm) Pro-Lock™ CT Safety Infusion Set	Predicate Device: 20G x ¾" (19mm) Pro-Lock™ CT Safety Infusion Set (K162271)
Design	Anti-coring Huber style needle for port septum access having a safety feature which that will prevent accidental needle sticks. The needle is connected to a conventional	Anti-coring Huber style needle for port septum access having a safety feature which that will prevent accidental needle sticks. The needle is connected to a conventional style

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	style extension set for attachment to standard IV/Drug infusion line sets.	extension set for attachment to standard IV/Drug infusion line sets.
Dimensions or Lengths	5/8"	¾"
Indications for Use	The Medcomp® Pro-Lock™ CT Safety Infusion Set is intended for use in the administration of fluids and drugs as well as blood sampling through implanted vascular access ports. The Medcomp® Pro-Lock™ CT Safety Infusion Set is also indicated for power injection of contrast media into the central venous system with implanted vascular access ports indicated for power injection. The maximum recommended infusion rate at 11.8 cPs is 5 ml/sec for 20 gauge non-coring Huber style needles.	The Medcomp® Pro-Lock™ CT Safety Infusion Set is intended for use in the administration of fluids and drugs as well as blood sampling through implanted vascular access ports. The Medcomp® Pro-Lock™ CT Safety Infusion Set is also indicated for power injection of contrast media into the central venous system with implanted vascular access ports indicated for power injection. The maximum recommended infusion rate at 11.8 cPs is 5 ml/sec for 20 gauge non-coring Huber style needles.
Intended Use	The Pro-Lock™ CT Safety Infusion Set is intended for use in the administration of fluids and drugs, as well as blood sampling through surgically implanted vascular ports.	The Pro-Lock™ CT Safety Infusion Set is intended for use in the administration of fluids and drugs, as well as blood sampling through surgically implanted vascular ports.
Gauge Sizes	20 GA	20 GA
Sterilization Method	EO	EO
Materials	**Cannula:** Stainless Steel **Female Luer:** PVC **Extension:** Pellethane **Clamp:** Polypropylene **Base:** Polypropylene **Sleeve:** PVC	**Cannula:** Stainless Steel **Female Luer:** PVC **Extension:** Pellethane **Clamp:** Polypropylene **Base:** Polypropylene **Sleeve:** PVC
Performance Testing	**Maximum Infusion Rate:** 11.8 cPs is 5 ml/sec for 20 gauge **Priming Volume:** 0.20cc **Maximum Flow Rate:** 5ml/second 325 psi max	**Maximum Infusion Rate:** 11.8 cPs is 5 ml/sec for 20 gauge **Priming Volume:** 0.20cc **Maximum Flow Rate:** 5ml/second 325 psi max

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7. **Bench / Performance Data / Non-Clinical Testing:**
The results of performance testing, in conjunction with the substantial equivalence claims, effectively demonstrate the proposed device, 20G x 5/8" (15mm) Pro-Lock™ CT Safety Infusion Set, is equivalent to the predicate device, 20G x ¾" (19mm) Pro-Lock™ CT Safety Infusion Set (K162271).

Table 6.2 Bench Testing and Reference Standards:

Test Performed	Test Method
Priming Volume	**Per Internal Test Method**
Gravity Flow	**ISO 10555-1: 2013** – *Incorporating corrigendum April 2014 – Intravascular catheters – Sterile and single-use catheters Part 1: General Requirements*
Needle Insertion/Extraction Force	ISO 10555-6: 2015 – *Intravascular catheters – Sterile and single-use catheters – Part 6: Subcutaneous implanted*
Air Leakage	ISO 8536-8: 2004 – *Infusion equipment for medical use – Part 8: Infusion equipment for use with pressure infusion apparatus*
Test Performed	**Test Method**
Liquid Leakage	**ISO 10555-1: 2013** – *Incorporating corrigendum April 2014 – Intravascular catheters – Sterile and single-use catheters Part 1: General Requirements,* **Annex C**
Luer Lock Fittings	ISO 594-2: 1998 – *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment*
Occlusion with Clamp	**Per Internal Test Method**
Extension Tensile and % Elongation	**ISO 10555-1: 2013** – *Incorporating corrigendum April 2014 – Intravascular catheters – Sterile and single-use catheters Part 1: General Requirements*
Power Injection Simulation	**ISO 10555-1: 2013** – *Incorporating corrigendum April 2014 – Intravascular catheters – Sterile and single-use catheters Part 1: General Requirements*
Port Septum/Needle Evaluation for Coring	**Per Internal Test Method**
Break Pull Test/ Static Load Pull Test	**ISO 10555-1: 2013** – *Incorporating corrigendum April 2014 – Intravascular catheters – Sterile and single-use catheters Part 1: General Requirements*
Needle to Extension Joint	**ISO 10555-1: 2013** – *Incorporating corrigendum April 2014 – Intravascular catheters – Sterile and single-*

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Pull	*use catheters Part 1: General Requirements*
Corrosion Resistance	**ISO 11070: 2014** – *Sterile single-use intravascular introducers, dilators and guidewires*
Shelf Life (3 years)	**ISO 11607-1: 2009+A1:2014-** *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials sterile barrier systems and packaging* **ASTM F1980-16,** *Standard guide for accelerated aging of sterile barrier systems for medical* **ISO 10555-1: 2013** – *Incorporating corrigendum April 2014 – Intravascular catheters – Sterile and single-use catheters Part 1: General Requirements* **ASTM F-1929-15-**, *Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration* **ASTM F-1140-** *Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages*
Shipping Test	**ISO 11607-1: 2009+A1:2014-** *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials sterile barrier systems and packaging* **ISTA-2A-2011** - *Performance Tests for Packaged-Products, Packaged-Products 150lb (68 kg) or Less* **ASTM F-1929-15-**, *Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration* **ASTM F-1140-** *Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages*
Simulated Use Study: Sharps Injury Prevention	**FDA's Guidance: Medical Devices with Sharps Injury Prevention Features**
Living Hinge Fatigue	**Per Internal Test Method**
Force at Break	**Per Internal Test Method**
Evaluation of Magnetic Field Interactions, Heating, and Artifacts	**ASTM F2052-15** – *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment* **ASTM F2119-07** – *Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants* **F2182-11a** – Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging

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	F2213-06 – *Standard test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment* **ASTM F 2503-13** – *Standard practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*

8. **Biocompatibility:**

Biocompatibility was performed on the final, finished Pro-Lock™ CT Safety Infusion Set per ISO 10993-1 for an externally communicating device, with indirect blood path exposure for a prolonged duration with the body, greater than 24 hours and less than 30 days. The biological endpoints include:

- Sensitization/Irritation: ISO 10993-10: 2010 *Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization*
- Acute Systemic Toxicity: ISO 10993-11: 2006 *Biological Evaluation of Medical Devices - Part 11: Tess for Systemic Toxicity*
- Cytotoxicity: ISO 10993-5: 2009 *Biological Evaluation of Medical Devices - Part 10: Tests for in vitro Cytotoxicity*
- Pyrogenicity: ISO 10993-11: 2006 *Biological Evaluation of Medical Devices - Part 11: Test for Systemic Toxicity*
- Hemocompatibility: ISO 10993-4: 2002 Amended 2006 *Biological Evaluation of Medical Devices - Part 4: Selection for tests for interactions with blood*
- Material Characterization: ISO 10993-18: 2005 *Biological Evaluation of Medical Devices - Part 18: Chemical Characterization of Materials*

9. **Summary of Substantial Equivalence:**

In conclusion, the proposed device, 20G x 5/8" (15mm) Pro-Lock™ CT Safety Infusion Set, is considered substantially equivalent to the predicate device, 20G x ¾" (19mm) Pro-Lock™ CT Safety Infusion Set (K162271) as demonstrated through non-clinical testing performed.