



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 26, 2017

Medcomp®
Ms. Courtney Nix
Regulatory Affairs Manager, North America and EU
1499 Delp Drive
Harleysville, Pennsylvania 19438

Re: K162271
Trade/Device Name: Pro-lock™ CT Safety Infusion Set
Regulation Number: 21 CFR 880.5570
Regulation Name: Single Lumen Hypodermic Needle
Regulatory Class: Class II
Product Code: PTI
Dated: March 20, 2017
Received: March 21, 2017

Dear Ms. 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K162271

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 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 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.

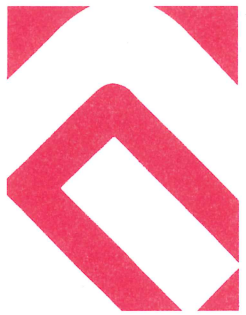
This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."



medCOMP

1499 Delp Drive

Harleysville, PA 19438

Tel: 215-256-4201

Fax: 215-256-1787

www.medcompnet.com

510(k) SUMMARY

Traditional 510K

K162271

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:

04/26/2017

2. Proposed or Subject Device Information:

Trade Name:

Pro-Lock™ CT Safety Infusion Set

Device:

Non-Coring (Huber) Needle

Product Code:

PTI

Regulation Name:

Single Lumen Hypodermic Needle

C.F.R. Section:

21 CFR 880.5570

Class:

II

**Regulation Medical
Specialty and Review
Panel:**

General Hospital

3. Predicate Device Information:

510(k) Number:

K132880

Trade Name:

Medcomp® Power Injectable Safety Huber
Needle

Device:

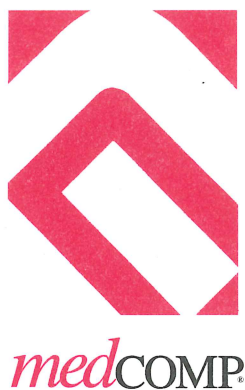
Non-Coring (Huber) Needle

Product Code:

PTI

C.F.R. Section:

21 CFR 880.5570



1499 Delp Drive

Harleysville, PA 19438

Tel: 215-256-4201

Fax: 215-256-1787

www.medcompnet.com

4. Device Description:

The 20G x 3/4" (19mm) Pro-Lock™ CT Safety Infusion Set is composed of a Huber style needle for port septum access having a safety feature designed to aid in the prevention accidental needle sticks when manually activated 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:

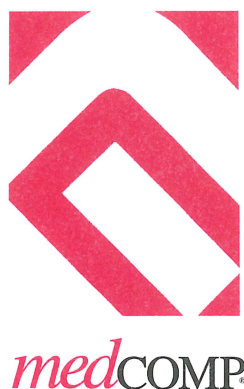
The 20G x 3/4" (19mm) Pro-Lock™ CT Safety Infusion Set is substantially equivalent to the predicate device, Medcomp® Power Injectable Safety Huber Needle (K132880), in terms of indications for use, intended use, fluid path materials, biocompatibility, basic design, performance, labeling, and manufacturing process.

The difference between the predicate device, Medcomp® Power Injectable Safety Huber Needle (K132880), and the 20G x 3/4" (19mm) Pro-Lock™ CT Safety Infusion Set are the changes to the clamp material from acetal to Polypropylene, and the ergonomics of the safety feature to allow better grip during safety feature activation.

The indications for use differ in regards to the name of the device. There are no other differences in the indications for use statements.

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

Device	Proposed Device: 20G x 3/4" (19mm) Pro-Lock™ CT Safety Infusion Set	Predicate Device: Medcomp® Power Injectable Safety Huber Needle (K132880)
--------	--	--



1499 Delp Drive

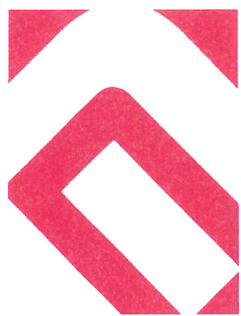
Harleysville, PA 19438

Tel: 215-256-4201

Fax: 215-256-1787

www.medcompnet.com

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 style extension set for attachment to standard IV/Drug infusion line sets.	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 extension set for attachment to standard IV/Drug infusion line sets.
Dimensions or Lengths	$\frac{3}{4}$ "	$\frac{1}{2}$ ", $\frac{3}{4}$ " 1", 1- $\frac{1}{2}$ "
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® Power Injectable Safety Huber Needle is intended for use in the administration of fluids and drugs as well as blood sampling through implanted vascular access ports. The Medcomp® Power Injectable Safety Huber Needle 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.
Gauge Sizes	20 GA	19, 20, 22 GA
Sterilization Method	EO	EO
Fluid Path Materials	Cannula: Stainless Steel Female Luer: PVC Extension: Pellethane	Cannula: Stainless Steel Female Luer: PVC Extension: Pellethane
Skin Contacting Materials	Clamp: Polypropylene Base: Polypropylene Sleeve: PVC	Clamp: Acetal 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: 0.18cc Maximum Flow Rate: 5ml/second 325 psi max



medCOMP

1499 Delp Drive

Harleysville, PA 19438

Tel: 215-256-4201

Fax: 215-256-1787

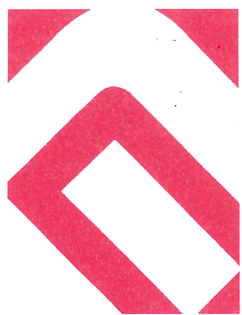
www.medcompnet.com

Patient Ergonomics	Lift required to engage safety lock, when locked needle is a blind hole, and catch for extension tubing	Lift and squeeze required to engage safety lock, when locked needle is in an open hole, and no catch for extension tube
---------------------------	---	---

9. 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 3/4" (19mm) Pro-Lock™ CT Safety Infusion Set, is equivalent to the predicate device, Medcomp® Power Injectable Safety Huber Needle (K132880).

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 Pull	ISO 10555-1: 2013 – Incorporating corrigendum April 2014 – Intravascular catheters – Sterile and single-use catheters Part 1: General Requirements



medCOMP

1499 Delp Drive

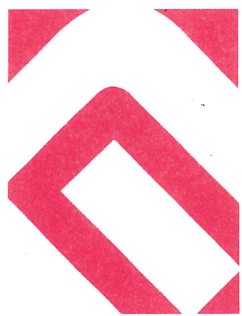
Harleysville, PA 19438

Tel: 215-256-4201

Fax: 215-256-1787

www.medcompnet.com

Corrosion Resistance	ISO 11070: 2014 – <i>Sterile single-use intravascular introducers, dilators and guidewires</i>
Shelf Life (3 years)	ISO 11607-1: 2009+A1:2014- <i>Packaging for terminally sterilized medical devices – Part 1: Requirements for materials sterile barrier systems and packaging</i> ASTM F1980-16, <i>Standard guide for accelerated aging of sterile barrier systems for medical</i> ISO 10555-1: 2013 – <i>Incorporating corrigendum April 2014 – Intravascular catheters – Sterile and single-use catheters Part 1: General Requirements</i> ASTM F-1929-15-, <i>Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration</i> ASTM F-1140- <i>Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages</i>
Shipping Test	ISO 11607-1: 2009+A1:2014- <i>Packaging for terminally sterilized medical devices – Part 1: Requirements for materials sterile barrier systems and packaging</i> ISTA-2A-2011 - <i>Performance Tests for Packaged-Products, Packaged-Products 150lb (68 kg) or Less</i> ASTM F-1929-15-, <i>Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration</i> ASTM F-1140- <i>Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages</i>
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 – <i>Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment</i> ASTM F2119-07 – <i>Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants</i> F2182-11a – <i>Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging</i> F2213-06 – <i>Standard test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment</i> ASTM F 2503-13 – <i>Standard practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment</i>



medCOMP

1499 Delp Drive

Harleysville, PA 19438

Tel: 215-256-4201

Fax: 215-256-1787

www.medcompnet.com

10. Biocompatibility:

Biocompatibility was performed on the final, finished 20G x $\frac{3}{4}$ " (19mm) 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. 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: Test 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*

11. Summary of Substantial Equivalence:

In conclusion, the proposed device, 20G x $\frac{3}{4}$ " (19mm) Pro-Lock™ CT Safety Infusion Set, is considered substantially equivalent to the predicate device, Medcomp® Power Injectable Safety Huber Needle (K132880) as demonstrated through non-clinical testing performed.