K132177

DEC 12 2013

Section 5 **510(k) SUMMARY** **Traditional 510K**

Submitter Information:

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 Tel: (215) 256-4201 Fax: (215) 256-9191
Contact:	Rosanna Severini Compliance Manager

Date Prepared:	June 28, 2013
Trade Name:	Medcomp® Gen III Power Injectable Port
Common Name:	Power Injectable, Implantable, Infusion Port
Classification Name:	Subcutaneous, implanted, intravascular infusion port and catheter
C.F.R. Sections	§880.5965 Product Code and Class: LJT, II
Predicate Devices:	K070003: Medcomp, Power Injectable Implantable Port, concurrence date May 15, 2007.

Device Description:

The Medcomp® Gen III Power Injectable Port includes the Dignity® Mini, Low Profile and Midsize and Pro-Fuse® Low Profile and Standard are subcutaneously implantable single fluid reservoir port offered with a choice of a silicone or polyurethane catheter either pre-attached by the manufacturer or attachable for application by the inserting physician. The Pro-Fuse® product line offers a round base while the Dignity® product line offers a shovel nose concaved sides and smooth contours. The Dignity® product line is offered in Midsize, which has a smaller base than the predicate, K070003. The Dignity® product line is offered in Low Profile, which is a smaller base than the Midsize therefore is smaller than predicate, K070003. The Dignity® product line is offered in Mini, it is the smallest offered profile.

Placement of the port is determined by the inserting physician based on patient anatomy and medical judgment. The port can be anchored with sutures in the port pocket for secure seating. The catheter lock provides securement of the catheter to the port stem. The port is accessed by inserting a non-coring needle through the skin into the self-sealing septum.

The base of the port is printed with the letters "CT" in reverse with radiopaque ink to signify that it can be used for power injection on contrast agents (orientation will appear correct under x-ray). Lot numbers are laser etched into the base of the port.

Power injection of contrast media, can be safely administered with a 19 or 20 gauge power injectable infusion non-coring needle at a maximum recommended infusion rate of 5 ml/s.

The implantable infusion port is packaged with the necessary accessories to facilitate catheter insertion.

Indications for Use:

The Medcomp® Gen III Power Injectable Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products and for the withdrawal of blood samples.
When used with a power injectable needle, the power injectable infusion port is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s with a 19 or 20 gauge non-coring power injectable needle.

Comparison to Predicate Devices:

The implanted port is substantially equivalent to the predicate devices cleared in K070003 in terms of intended use, anatomical location, basic design, materials, performance, labeling, manufacturing process and method of sterilization.

Port Types	Port Body and Catheter Options	Comparison to Predicate (K070003)
STANDARD PRO-FUSE ®	Purple plastic cap and base. **Catheters Offered:** 9.6F Silicone 8F Polyurethane	Inception design of Medcomp Infusion CT Ports. The line began with the Standard Pro-Fuse®.
LOW PROFILE PRO-FUSE®	Purple plastic cap and base. **Catheters Offered:** 8F Polyurethane 6.6F Polyurethane 5F Polyurethane Silicone Filled Suture Holes available.	The Pro-Fuse® Low Profile Offers a smaller port body size compared to the predicate (K070003), Standard Pro-Fuse® port. The base is smaller and smaller height than predicate, K070003.
MID-SIZE DIGNITY®	Purple plastic cap and base. **Catheters Offered:** 9.6F Silicone 8F Polyurethane 6.6F Polyurethane 5F Polyurethane Silicone Filled Suture Holes available.	The Dignity® Midsize offers a different port body shape functions equivalent to predicate (K070003), Standard Pro-Fuse® port. The port body offers a shovel nose feature and smooth contours for increased patient comfort and ease of insertion. The base is narrower than the predicate. K070003.
LOW PROFILE DIGNITY®	Purple plastic cap and base. **Catheters Offered:** 8F Polyurethane 6.6F Polyurethane 5F Polyurethane Silicone Filled Suture Holes available.	The Dignity® Low Profile offers a different port body shape functions equivalent to predicate (K070003), Standard Pro-Fuse® port. The port body offers a shovel nose feature and smooth contours for increased patient comfort and ease of insertion. The base is narrower than the predicate, K070003 and the Midsize Dignity.
MINI DIGNITY®	Purple plastic cap and base. **Catheters Offered:** 8F Polyurethane 6.6F Polyurethane 5F Polyurethane Silicone Filled Suture Holes available.	The Dignity® Mini offers a different port body shape functions equivalent to predicate (K070003), Standard Pro-Fuse® port. The port body offers smooth contours and is our lowest profile. The base is smaller than the predicate, K070003 including smaller than the Midsize and Low Profile Dignity.

The unique characteristic of the Gen III implanted port is a universal catheter lock. The new catheter lock is universal in form therefore eliminating the need for inserting physicians to determine which way the lock must be connected to the port.

Bench / Performance Data:

In vitro testing was performed on the Power Injectable, Implantable Infusion Port to assure reliable design and performance in accordance with the FDA's "*Guidance on 510(k) Submissions for Implanted Infusion Ports*" dated October 1990. Verification testing and performance testing performed according to the referenced standards as well as in accordance with in-house protocols.

The following testing was performed on all configurations Pro-Fuse Standard and Low Profile, Dignity Low Profile, Midsize and Mini, in accordance with requirements of ISO 10555-1 for all configurations listed in pursuant of this application to market.

Power Injection Simulation
Elongation & Tensile
Priming Volume
Gravity Flow
Stem Break Force
Cap/Base Bond Integrity
Catheter Lock Integrity
Clearance Volume
Needle Insertion/Extraction Force
Reservoir Pressure
Static Burst Pressure

The results of these tests in conjunction with the substantial equivalence claims effectively demonstrate the proposed devices are equivalent to the predicate device, K070003.

Biocompatibility:

Testing for all materials used for the Power Injectable, Implantable Infusion Port has been submitted in previously cleared Medcomp device predicate K070003. All biocompatibility testing demonstrates the materials used meet the requirements of ISO 10993.

Technological Characteristics:

Technological similarities between the proposed devices and predicate devices remain the same. The primary difference between the predicate and Gen III implanted port is the universal lock. This catheter lock is universal in form and capable of being placed bi-directionally. This provides a unique feature while maintaining the same functional characteristics of the predicate device.

Summary of Substantial Equivalence:

The proposed devices meet the performance criteria of design verification as specified by ISO standards, guidance documents and internal test protocols. The proposed device has the same intended use, operation and function as the predicates. There are no differences that raise new issues of safety and effectiveness. The proposed device is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 12, 2013

Medical Components, Incorporated
Ms. Rosanna Severini
Regulatory Specialist
1499 Delp Drive
HARLEYSVILLE PA 19438

Re: K132177

Trade/Device Name: Medcomp® Gen III Power Injectable Port
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: November 11, 2013
Received: November 12, 2013

Dear Ms. Severini:

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.

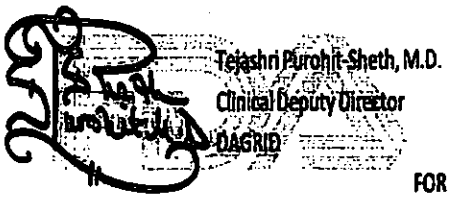
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,



FOR

Erin I. Keith, M.S.
Acting Division 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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132177

Device Name
Medcomp® Gen III Power Injectable Port

Indications for Use *(Describe)*
The Medcomp® Gen III Power Injectable Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products and for the withdrawal of blood samples.

When used with a power injectable needle, the power injectable infusion port is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s with a 19 or 20 gauge non-coring power injectable needle.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Richard C. Chapman
Date: 2013.12.12 10:16:39 -05'00'