



Food and Drug Administration
10903 New Hampshire Avenue
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March 15, 2016

Medcomp (Medical Components)
Ms. Courtney Nix
Regulatory Associate
1499 Delp Drive
Harleysville, Pennsylvania 19438

Re: K153238

Trade/Device Name: Dignity[®] Dual Port
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, implanted, intravascular infusion port and catheter
Regulatory Class: II
Product Code: LJT
Dated: February 9, 2016
Received: February 12, 2016

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 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,

 Tina Kiang
-S

for Erin I. Keith, M.S.
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)

K153238

Device Name

Dignity® Dual Port

Indications for Use (Describe)

The Dignity® Dual Port is a power injectable implantable infusion port that is indicated for patient therapies requiring repeated access to the vascular system. The Dignity® Dual Port 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 Dignity® Dual 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. The maximum recommended infusion rate is 2 ml/s with a 22 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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A. Submitter Information:

Submitter: MEDCOMP®
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Contact: Courtney Nix
 Regulatory Associate
 Cnix@medcompnet.com

Date Prepared: March 11, 2016

B. Trade Name: Dignity® Dual Port

Common Name: Power Injectable, Implantable, Infusion Port

Product Code : LJT - Subcutaneous, Implanted, Intravascular Infusion Port and Catheter

C.F.R. Section: 21 CFR 880.5965, Class II

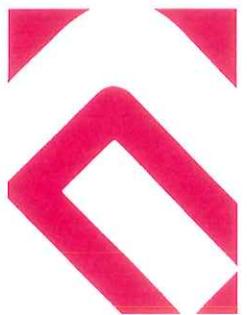
Classification Panel: General Hospital

C. Predicate Devices: K090512 C.R. Bard, Inc. PowerPort© duo M.R.I.™ Implanted Port with 9.5 Fr, Dual Lumen ChronoFlex® Catheter, class II 880.5956**D. Reference Devices:** K070003 Medcomp®, Power Injectable Implantable Infusion Port; Pro-Fuse®, class II 880.5965

K120281 Medcomp®, Dignity® Power Injectable Titanium Port, class II 880.5965

E. Purpose for Submission: Expansion of Medcomp®'s Dignity® product line to include an in-line dual reservoir point with injection capabilities.**F. Device Description:**

The Dignity® Dual power injectable implantable infusion port is an implantable access device designed to provide repeated access to the vascular system. Port access is performed by percutaneous needle insertion using a non-coring needle. **Power injection is performed using a power injectable needle only.** The Dignity® Dual Port device consists of two primary components: an injection port with a self-sealing septa and a radiopaque catheter. The Dignity® Dual Ports can be identified subcutaneously by feeling the top of the septum and the top rim of the port



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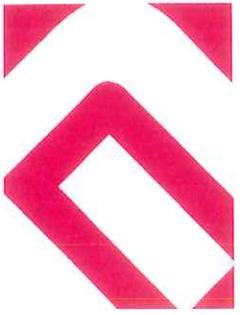
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housing. Power Injectable Implantable Infusion Ports can be identified by the letters "CT" under radiographic imaging.

The Dignity® Dual Port will be marketed in four kit configurations, which are listed below:

- 9.5F Standard Port Kit (Catalog number MRDP95ADN)
- 9.5F Port Kit with Micro-Stick (Catalog number MIDP95ADN)
- 9.5F Standard Port Kit with Silicone Filled Suture Holes (Catalog number MRDP95ADS)
- 9.5F Port kit with Silicone Filled Suture Holes and with Micro-Stick (Catalog number MIDP95ADS)

G. Indications for Use:

The Dignity® Dual Port is a power injectable implantable infusion port that is indicated for patient therapies requiring repeated access to the vascular system. The Dignity® Dual Port 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 Dignity® Dual 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. The maximum recommended infusion rate is 2 ml/s with a 22 gauge non-coring power injectable needle.

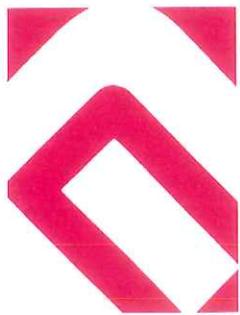
H. Comparison to Predicate Devices:

The Dignity® Dual Port is substantially equivalent to the predicate device, C.R. Bard PowerPort® (K090512), in terms of intended use, anatomical location, basic design, performance, labeling, manufacturing process and method of sterilization.

The Dignity® Dual power injectable implantable infusion port, is equivalent to the Medcomp® reference devices, Medcomp® Pro-Fuse® (K070003) and Medcomp® Dignity® Power Injectable Titanium Port (K120281), in materials.

The difference between the reference device, Dignity® Power Injectable Titanium Port (K120281), and the Dignity® Dual Port assembly is that the Dignity® Dual Port has a polysulfone cap, base, two silicone septa and a titanium insert, while the titanium port is comprised of a one piece titanium housing and silicone septum. The Dignity® Dual Port utilizes a titanium insert to connect the distal reservoir to the catheter. Both ports use the same grade of titanium.

The difference between the Dignity® Dual Port and the predicate, Bard Access Systems, PowerPort™ duo M.R.I™ Implanted Port (K090512), is that the PowerPort™ duo M.R.I™ is a side-by-side reservoir design, whereas the Dignity® Dual Port has an in-line reservoir design.



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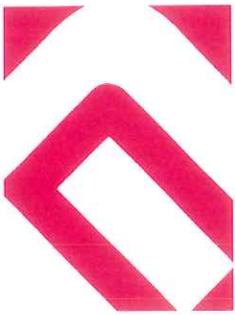
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Table 1: 510(K) Summary: Design Comparison Matrix

Device	Proposed Dignity® Dual Port (K153238)	C.R. Bard PowerPort® (K090512)	Substantially Equivalent Comparison
Design	Double lumen open ended Dual reservoir Power injection	Double Lumen Dual reservoir Power Injection	Equivalent
Dimensions	Bases Fits within: 41mm x 12mm Internal Volume: 0.7ml and 0.6 ml Depth Marking every 1cm	Bases Fits within: 29mm x 39mm Internal Volume: 0.6 ml each reservoir Depth Marking every 1cm	Equivalent
Indications for use	<p>The Dignity® Dual Port is a power injectable implantable infusion port that is indicated for patient therapies requiring repeated access to the vascular system. The Dignity® Dual Port can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.</p> <p>When used with a power injectable needle, the Dignity® Dual 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. The maximum recommended infusion rate is 2 ml/s with a 22 gauge non-coring power injectable needle.</p>	<p>PowerPort™ Implanted 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.</p> <p>When used with a PowerLoc™ Safety Infusion Set, The PowerPort™ device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s.</p> <p>(From 510(k) Summary K090512)</p>	Equivalent
Catheter Size	9.5F Double Lumen ChronFlex Polyurethane Catheter	9.5F Double Lumen ChronFlex Polyurethane Catheter	Equivalent
Sterilization	ETO ANSI/AAMI/ISO 11135-1:2007 SAL 10 ⁻⁶	ETO Reference Not Sited in published 510(k) Summary	Equivalent
Power Injectable	Power Injectable Rate: 5 ml/s	Power Injectable Rate: 5 ml/s	Equivalent
Materials	Thermoplastic Polymer Silicone Polyurethane Titanium Polycarbonate	Plastic Silicone Polyurethane	Equivalent to References Devices; Medcomp® Pro-Fuse® (K070003) and Medcomp® Dignity® Power

Dignity Dual Port- 510K Summary



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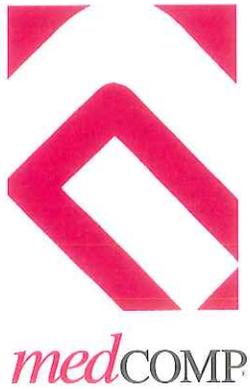
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			Injectable Titanium Port (K120281)
MRI	MRI Conditional	MRI Conditional	Equivalent
Performance Testing	Power Injection: 19Ga 4.9ml/s 20Ga 4.9ml/s 22Ga 1.9ml/s Infusion Testing: 1600ml/hr Catheter Lock Disengagement: 6.9 lb Needle Insertion: 19Ga 3.8lb 22Ga 3.6 lbs Gravity Flow: 1760 ml/hr	Power Injection: 19Ga 4.9ml/s 20Ga 4.9ml/s 22Ga 1.9ml/s Infusion Testing: 1700ml/hr Catheter Lock Disengagement: 10 lbs Needle Insertion: 19Ga 2.88lb 22Ga 2.05 lbs Gravity Flow: 1680 ml/hr	Equivalent

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

The results of performance testing, in conjunction with the substantial equivalence claims, effectively demonstrate the proposed device is equivalent to the predicate devices. The performance testing was performed in accordance with the following standards:

- BS EN ISO 10555-1: 2013; Intravascular Catheters – Sterile and Single-use Catheters Part 1: General Requirements
- ISO 10555-3: 2013; Intravascular Catheters – Sterile and Single-Use Catheters – Part 3: Central Venous Catheters (General Plastic Surgery/General Hospital)
- BS EN ISO 10993-1; 2009: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (Biocompatibility)
- BS EN ISO 11135; Second Edition 2014; Sterilization of health-care products - Ethylene oxide-Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 10555-6: 2015; Intravascular Catheters – Sterile and Single-use Catheters – Part 6: Subcutaneous implanted ports
- ASTM F2213-06: (Reapproved 2011), standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment. (Materials)
- ASTM F2129-08: Standard test method for conducting cyclic potentiodynamic polarization measurements to determine the corrosion susceptibility of small implant devices. (Materials)
- ASTM F2052-14: standard test method for measurement of magnetically induced displacement force on medical devices in the magnetic resonance environment. (Materials)
- ASTM F2503-13: standard practice for marking medical devices and other items for safety in the magnetic resonance environment. (Materials)



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J. Biocompatibility:

Materials of the Dignity® Dual Port are equivalent to the cleared, reference devices; Medcomp®, Power Injectable Implantable Infusion Port; Medcomp® Pro-Fuse® (K070003) and Medcomp® Dignity® Power Injectable Titanium Port (K120281). Biocompatibility on both reference devices we performed per ISO 10993-1, for a permanent implant device with tissue and both indirect and direct blood contact.

The Dignity® Dual Port is comprised of a polysulfone cap (with silicone filled suture holes, or open suture holes), two silicone septa, and a polysulfone base assembly with a titanium tube that provides a channel from the stem to the distal reservoir. The reservoir is plastic (polysulfone). The Dignity® Dual catheter locking assembly (makrolon/pellethane) locks the chronoflex lumen to the plastic stem of the Dignity® Dual Port. The materials that the Dignity® Dual Port is constructed of are the same as those cleared in the Power Injectable Implantable Infusion Port Pro-Fuse™ (K070003), and the same formulation of titanium as cleared in the Dignity® Power Injectable Titanium Port (K120281). Therefore, as mentioned above, Medcomp® intends to use approved Medcomp® devices, Medcomp® Pro-Fuse® (K070003) and Medcomp® Dignity® Power Injectable Titanium Port (K120281), for biocompatibility testing results per ISO 10993-1, for a permanent implant device with tissue and both indirect and direct blood contact. Hence, all biocompatibility testing demonstrates the materials used meet the requirements of ISO 10993-1 and a summary of prior testing is contained in section 15.

K. Summary of Substantial Equivalence:

In conclusion, the proposed device, The Dignity® Dual power injectable implantable infusion port, is equivalent to the predicate device, C.R. Bard PowerPort® (K090512), in intended use, design, function, and performance. The proposed device, The Dignity® Dual power injectable implantable infusion port, is equivalent to the Medcomp® references devices, Medcomp® Pro-Fuse® (K070003) and Medcomp® Dignity® Power Injectable Titanium Port (K120281), in materials.

The proposed device, The Dignity® Dual power injectable implantable infusion port, meets the performance criteria of design verification as specified by ISO standards, guidance documents and internal test protocols. The proposed device is substantially equivalent to the indicated legally marketed predicate and reference devices as defined in paragraph above.