K110424

NOV 3 0 2011

Section 5 510(k) SUMMARY

A. Submitter Information:

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 (215) 256-4201 Telephone (215) 256-9191 Fax
Contact:	Jean Callow, Regulatory Specialist
Date Prepared:	February 11, 2011

B. Trade Names: Dignity™ Mini CT Port and Dignity™ Low Profile CT Port

Common Name:	Power Injectable, Implantable, Infusion Port
Classification Name:	Subcutaneous, Implanted, Intravascular Infusion Port and Catheter Long Term
Classification:	LJT
Classification Advisory Committee:	General Hospital
C.F.R. Section:	880.5965
Device Classification:	II

C. Predicate Devices:

K070003 Power Injectable Port
Medcomp, Concurrence date May 15, 2007
K952435, Celsite® Pediatric Venous Port,
B. Braun Medical, Inc.

D. Device Description:

The Dignity™ CT implantable infusion ports are subcutaneously implantable single fluid reservoir ports offered with a polyurethane (5F) catheter either pre-attached by the manufacturer or attachable for application by the inserting physician in a choice of two kit configurations. 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 ports are offered in a Mini or Low Profile design with power injection capabilities.

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. The rigid top half of the port centers the silicone septum and aids in locating the implanted device under the skin.

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 and a maximum pressure setting of 300 psi.

A 22 gauge needle can be used at 2 ml/sec with a maximum pressure setting of 300 psi.

The implantable infusion port is packaged with the necessary accessories to facilitate catheter insertion in either a standard or micro-puncture kit.

E. Intended Use:

The CT Power Injectable Implantable Infusion Ports are indicated for pediatric 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.

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.

F. Technological Comparison to Predicate Devices:

The ports are substantially equivalent to the predicate devices in terms of intended use, insertion method, anatomical location, design, performance, materials, labeling and method of sterilization.

G. Safety and Effectiveness / Performance Data:

In vitro testing was performed on the ports 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.

Clinical studies were not deemed necessary since in vitro testing was sufficient to demonstrate safety and effectiveness by way of comparison to legally marketed predicate devices. This device presents no known additional risks to the patient that are not well documented and for which there is already a prescribed therapy.

H. Biocompatibility:

Materials have been used under previously approved 510k's. Biocompatibility testing demonstrated that the materials used meet the requirements of ISO 10993 for a permanent implantable tissue and blood contact device. All materials present no unusual or unacceptable risk to the patient.

I. Summary of Substantial Equivalence:

Performance data indicated the performance and materials of the Mini CT Port is equivalent to the claims of the currently marketed K070003 Medcomp Power Injectable Port and K952435, Celsite® Pediatric Venous Port, B. Braun Medical, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ms. Jean Callow
Regulatory Specialist
Medical Components, Incorporated
1499 Delp Drive
Harleysville, Pennsylvania 19438

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Re: K110424
Trade/Device Name: CT Power Injectable Implantable Infusion Port
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: November 21, 2011
Received: November 22, 2011

Dear Ms. Callow:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110424

Device Name: ___ CT Power Injectable Implantable Infusion Port_____

Indications for Use:

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman 11/29/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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