K093309

NOV 24 2009

510(k) Summary

PRO-LINE® CT Pressure Injectable CVC
Summary of Safety and Effectiveness
Prepared October 21, 2009

General Information:

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 Phone: (215) 256-4201 Fax: (215) 256-9191
Contact:	Jean Callow Regulatory Specialist
Device Trade Name:	PRO-LINE® CT Pressure Injectable CVC
Common Name:	Percutaneous, implanted, long-term intravascular catheter
Classification Name:	LJS - Catheter, Intravascular, Therapeutic, Long-Term Greater than 30 Days
CFR Reference:	21 CFG 880.5970, Class II
Classification Panel:	General Hospital

Predicate Devices:

Device Trade Name:	PRO-LINE® CT Pressure Injectable CVC PRO-PICC® CT
Common Name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	LJS –Catheter, Intravascular, Therapeutic, Long-Term Greater than 30 Days
CFR Reference:	21 CFR 880.5970, Class II
Classification Panel:	General Hospital
Premarket Notification:	K053345, concurrence date March 17, 2006 K091953, concurrence date September 16, 2009.

Performance Standards: Performance standards have not been established by FDA under section 514 of the Federal Food, Drug, and Cosmetic Act.

Indications for Use: Indications for Use: The Medcomp PRO-LINE® CT Power Injectable CVC is indicated for short or long term access to the central venous system. It is designed for administering I.V. fluids, blood products, drugs and parenteral nutrition solutions, as well as blood withdrawal and power injection of contrast media. The maximum recommended infusion rate is 5cc/sec. The maximum pressure of power injectors used with the PRO-LINE® CT Power Injectable CVC may not exceed 300 psi.

Device Description:

- Designed for central vein catherization

- Comprised of a polyurethane material with purple pigment to indicate it for power injection.
- The lumen is connected to the extensions by a hub with a suture wing for placement.
- Depth markings on the lumen and French size on the hub.
- Clamps are provided on the extension tubes to prevent air/fluid communication.
- A female luer connector provides the connection for intravenous administration.
- Maximum recommended pressure limit setting 300 psi.
- Maximum indicated power injection flow rate 5cc/sec.

Safety and Performance Tests

Biocompatibility requirements of ISO 10993 *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing* for externally communicating, blood contacting, long-term devices were met. All materials used in the manufacture of the PRO-PICC® were previously cleared for similar applications by Medcomp, Inc.

Performance testing of the PRO-PICC® was conducted in accordance with the following international standards:

- *ISO 10555-1: 1997, Sterile Single Use-Intravascular Catheters, General Requirements*
- *ISO 594-2: Conical Fittings with a 6% (Luer) Taper for Syringes, Needles, and Certain Other Medical Equipment – Part 2: Lock Fittings*

Subject product testing has yielded acceptable safety and performance outcomes.

The results of these tests, in conjunction with the substantial equivalence claims effectively demonstrate that the PRO-LINE® CT Pressure Injectable CVC is substantially equivalent to the cited predicate device.

Summary of Substantial Equivalence

Based on the indications for use and safety and performance testing, the PRO-LINE® CT Pressure Injectable CVC meets the requirements that are considered for its intended use and is substantially equivalent in design materials, sterilization, and indications for use to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

NOV 24 2009

Ms. Jean Callow
Regulatory Specialist
Medcomp
1499 Delp Drive
Harleysville, Pennsylvania 19438

Re: K093309
Trade/Device Name: PRO-LINE™ CT Power Injectable CVC
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: October 21, 2009
Received: October 28, 2009

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.

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,

for

Susan Runner, D.D.S., M.A.
Acting Division 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): K093309

Device Name: PRO-LINE™ CT Power Injectable CVC

Indications for Use: The Medcomp PRO-LINE™ CT Power Injectable CVC is indicated for short or long term access to the central venous system. It is designed for administering I.V. fluids, blood products, drugs and parenteral nutrition solutions, as well as blood withdrawal and power injection of contrast media. The maximum recommended infusion rate is 5cc/sec. The maximum pressure of power injectors used with the PRO-LINE™ CT Power Injectable CVC may not exceed 300 psi.

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)

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

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