MAR 17 2006

K053345

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: November 30, 2005

B. Trade Name:

Medcomp® PRO-LINE™ CT Power Injectable CVC

Common Name: Catheter, Intravascular, Therapeutic, Long-Term

Classification: LJS

C.F.R. Section: 880.5970 Class II

C. Predicate Device:

C.R. Bard, Inc. K033389 PowerPICC™ Catheters and
C.R. Bard, Inc. K051417 6Fr DL PowerHohn™ and PowerLine™ Catheter

D. Device Description:

The Medcomp® PRO-LINE™ CT Power Injectable CVC's are designed for central venous catheterization. The PRO-LINE™ CT Power Injectable CVC lumen is comprised of a soft radiopaque polyurethane material. The lumen is connected to the extensions via a soft pliable hub with suture wing for secure placement. Cuff attachment to the lumen provides for tissue ingrown. Clamps are provided on the extension tubes to prevent air/fluid communication. Female luer connectors provide the connection for intravenous administration. Purple colorant has been added to the catheter materials to differentiate it from other non-power injectable catheters and identify it as a power injectable catheter. The extensions also are printed with the words power injectable.

The PRO-LINE™ CT Power Injectable CVC's are available in 5F single lumen and 6F double lumen version. The catheters are 60 cm long with depth markings in 5cm increments. Stylet and adaptor sideport is provided to assist in catheter insertion.

The catheter product line is packaged with the necessary accessories to facilitate catheter insertion.

E. Intended Use:

The Medcomp PRO-LINE™ CT Power Injectable CVC is indicated for short or long term access to the central venous system. They are 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.

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The Medcomp PRO-LINE™ CT Power Injectable CVC is substantially equivalent to the predicate devices in terms of intended use, insertion method, anatomical location, design,
performance, labeling, manufacturing process and method of sterilization.

G. Performance Data:

In vitro testing was performed on the Medcomp PRO-LINE™ CT Power Injectable CVC to assure reliable design and performance in accordance with ISO 10555-1 and 10555-3. Testing includes air/liquid leakage, cuff shear, force at break, elongation, gravity flow, static burst pressure, high pressure injection flow rate and chemical testing.

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 device.

Biocompatibility testing on the Medcomp PRO-LINE™ CT Power Injectable CVC demonstrates that the materials used meet the requirements of ISO 10993 for a permanent contact device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2006

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

Re: K053345
Trade/Device Name: PRO-LINE™ CT Power Injectable CVC
Regulation Number: 880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Regulatory Class: II
Product Code: LJS
Dated: February 17, 2006
Received: February 21, 2006

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 (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); 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.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K053345

Indications for Use

510(k) Number (if known): _053345_____

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 of Cardiology, General Hospital, Infection Control, Dental Devices

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