

APR 27 2005

510(k) Summary of Safety and Effectiveness

Submitted by: B. Leon Wilson
Quality Manager
Carolina Medical, Inc.
157 Industrial Drive
King, NC 27021 USA

Telephone #: (336) 983-5132
Facsimile #: (336) 983-8992

Date Prepared: January 28, 2005

Trade Name: Infiltration Pump

Common Name: Infiltration Pump

Classification Name: Infusion Pump
21 CFR 880.5725 (2004), Product Code FRN

Establishment Registration Number:

Carolina Medical, Inc. is located at 157 Industrial Drive. We are registered with the Food and Drug Administration as Establishment Number 1017913.

Indications for Use:

The Infiltration Pump indications for use are lipoplasty general tumescent infiltration to include body contouring. The Infiltration Pump is not intended for intravenous use.

Device Description:

The principles of operation and technology incorporated in the Infiltration Pump are equivalent to peristaltic infiltration/irrigation devices, which use peristalsis-type action to move fluid through a tube by alternating mechanical squeezing of fluid-filled tubing with a roller.

The Infiltration Pump uses a multiple roller pump and a mechanical tubing clamp to squeeze and hold tubing and assist in moving fluid from an IV fluid bag to the infiltration site. As with all peristaltic pumps, the Infiltration Pump contacts only the tubing and never directly contacts the fluid, thus fluid sterility cannot be compromised by the pumping action.

Substantial Equivalence Claim:

The principles of operation and technology incorporated in the Carolina Medical Infiltration Pump are similar to other infiltration/irrigation devices with the function to deliver fluid with a roller, which the FDA has found to be substantially equivalent to devices as listed below:

Product:	PSI-TEC Peristaltic Infiltration Pump
Manufacturer:	Byron Medical, Inc.
510(k) Number:	K040149
Substantial Equivalence Date:	June 3, 2004
Substantial Equivalence Letter:	See Appendix A

Product:	Klein Surgical Infiltration Pump, Model KIP-II
Manufacturer:	HK Surgical, Inc.
510(k) Number:	K031432
Substantial Equivalence Date:	August 7, 2003
Substantial Equivalence Letter:	See Appendix A

-end of summary-



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 2005

Mr. Leon Wilson
Quality Manager
California Medical, Incorporated
157 Industrial Drive
P.O. Box 307
King, North Carolina 27021-0307

Re: K050324
Trade/Device Name: Infiltration Pump
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: February 7, 2005
Received: February 9, 2005

Dear Mr. Wilson:

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 such 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 begin 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/industry/support/index.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

Enclosure

Indications for Use

510(k) Number (if known):K050324

Device Name: Infiltration Pump

Indications for Use:

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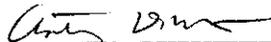
Prescription Use √
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use N/A
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF 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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