K980738

JUN 16 1998

Byron Medical Confidential - TRADE SECRET

510(k) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92

The assigned 510(k) number is: K980738

Submitted by: Steve Bollinger
V.P. Research and Development
Byron Medical, Inc.
3280 East Hemisphere Loop
Tucson, AZ 85706

Telephone #: (520) 573-0857
Facsimile #: (520) 746-1757

Date Prepared: 17 February 1998

Establishment Registration Number: Byron Medical is located at 3280 East Hemisphere Loop, Tucson, AZ 85706. We are registered with the Food and Drug Administration as Establishment Number 2025576.

Classification Name:

Irrigating Syringe
21 CFR § 880.6960 (1997)

Piston Syringe
21 CFR § 880.5860 (1997)

Infusion Pump
21 CFR § 880.5725 (1997)

Jet Lavage
21 CFR § 880.5475 (1997)

Common/Usual Name: Syringe Irrigation/Infiltration Pump

Proprietary Name: Psi-Tec Syringe Infusion Pump

Indication for Use: General surgical fluid irrigation and infiltration.

510(k) SUMMARY (cont.)

Device Description: The principles of operation and technology incorporated in the Psi-Tec Syringe Infusion Pump and accessories are to provide controlled fluid delivery by utilizing a disposable, pneumatically driven syringe cartridge attached to tubing, that can propel and monitor fluid volumes delivered into a surgical site by the system.

Substantial Equivalence Claim: The principles of operation and technology incorporated in the Byron Medical Psi-Tec Syringe Infusion Pump and accessories are similar to other irrigation devices, with the function to deliver fluid to a surgical site, which the FDA has founded to be substantially equivalent to pre-amendment devices as outlined below.

Product: Ackrad Fluid Connecting Set
Manufacturer: Ackrad Laboratories, Inc.
510(k) Number: K820937
Substantial Equivalence Date: 26 April 1982
Substantial Equivalence Letter is presented in Exhibit **N.**

Product: Big Bag 3000 Pressure Infusor
Manufacturer: Byron Medical, Inc.
510(k) Number: K973133
Substantial Equivalence Date: 12 September 1997
Substantial Equivalence Letter is presented as Exhibit **O.**

Product: Nezhat-Dorsey Hydro-Dissection Universal Bag Squeezer
Manufacturer: Davol, Inc.
510(k) Number: K953574
Substantial Equivalence Date: 29 September 1995
Substantial Equivalence Letter is presented as Exhibit **P.**

-end of summary-

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 1998

Mr. Steve Bollinger
V.P. Research and Development
Byron Medical
3280 East Hemisphere Loop, Suite 100
Tucson, Arizona 85706

Re: K980738
Trade Name: Psi-Tec Syringe Pump
Regulatory Class: II
Product Code: FRN
Dated: March 25, 1998
Received: March 31, 1998

Dear Mr. Bollinger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control, and General Hospital Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K980738

Device Name: Psi-Tec Syringe Infusion Pump and Accessories

Indications for Use:

The Psi-Tec Syringe Infusion Pump and accessories indications for use are for General Fluid Irrigation/Infiltration.

(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 Dental, Infection Control,
and General Hospital Devices
510(k) Number K980738

Prescription Use ____
(Per 21 CFR 801.109

Over-The Counter Use X

(Optional Format 1-2-96)