MAR - 5 1998

Byron Medical Confidential - TRADE SECRET K980392

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:_____

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: 26 January, 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:

Aspirator, Apparatus, Suction, Operating Class II
Room, Wall Vacuum Powered
21 CFR § 880.6740 (1997)

Aspirator, Apparatus, Suction, Ward Use, Class II
Portable, AC -Powered
21 CFR § 878.4780 (1997)

Common/Usual Name: Aspirator, General

Proprietary Name: **Psi-Tec Aspirator**

510(k) SUMMARY (cont.)

Indication for Use: General surgical fluids, exudate, soft tissue, and general tissue removal from surgical sites.

Device Description: General aspirator(s), which use an electrically (AC) driven vacuum pump generating a negative pressure for evacuating surgical waste. The Psi-Tec Aspirator 2 also has the capability to capture the waste air "exhaust" (that creates the negative pressure) in an enclosed container. This now, contained and pressurized air, can then be utilized for driving other devices requiring the use of pressurized air.

Substantial Equivalence Claim: The PSI-TEC Aspirator(s) are substantially equivalent to the following legally-marketed devices ("Predicate Devices") in terms of safety, effectiveness, and intended use:

Product: **General Aspirator**
Manufacturer: Kolster Methods
510(k) Number: K895761
Substantial Equivalence Date: Unknown

Product: **Grams Aspirator**
Manufacturer: Grams Medical
2443 Norse Ave,
Costa Mesa, CA92627
510(k) Number: Unknown
Substantial Equivalence Date: Unknown

Product: **Aspirator and Aspirator II**
Manufacturer: Wells Johnson Company
8075 E. Research Court,
Suite 101
Tucson, AZ 85710
510(k) Number: Unknown
Substantial Equivalence Date: Unknown

510(k) SUMMARY (cont.)

Substantial Equivalence Claim (CONT.):

Product:	**General Aspirator**
Manufacturer:	Mentor Corporation 5425 Hollister Ave. Santa Barbara, CA 931111
510(k) Number:	Unknown
Substantial Equivalence Date:	Unknown

-end of summary-

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Steve Bollinger
Vice President, Research and Development
Byron Medical, Incorporated
3280 East Hemisphere Loop
Tucson, Arizona 85706

MAR - 5 1998

Re: K980392
Trade Name: PSI-TEC Aspirators
Regulatory Class: II
Product Code: BTA and JCX
Dated: January 26, 1998
Received: February 2, 1998

Dear Mr. Bollinger:

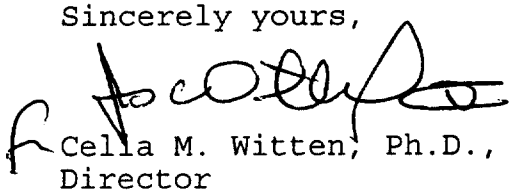
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined these devices are substantially equivalent (for the indications for use stated in the enclosures) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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 requirement, 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 devices 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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) 594-4595. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

CONFIDENTIAL

510(k) Number (if known): K980392

Device Name: **The PSI-TEC Aspirator(s)**

Indications for Use:

The PSI-TEC Aspirator(s) indications for use are general surgical fluids, exudate, soft tissue, and general tissue removal from surgical sites.

(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 General Restorative Devices
510(k) Number K980392

Prescription Use X
(Per 21 CFR 801.109

Over-The Counter Use ___

(Optional Format 1-2-96)