

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: K974295

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: 12 November 1997

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: Catheter, Irrigation
21 CFR § 878.4200 (1997)

Tubing, Non-Invasive
21 CFR § 884.1720 (1997)

Common/Usual Name: Aspiration and Irrigation Tubing

Proprietary Name: Byron Medical Aspiration (HI-VAC) and Infiltration / Irrigation (LAM) Tubing

Indication for Use: General surgical aspiration and fluid irrigation/ infiltration.

000000025

Byron Medical Confidential - TRADE SECRET

510(k) SUMMARY (cont.)

Device Description: The principles of operation and technology incorporated in the Tubing are equivalent to other standard surgical tubing that acts as a pathway between the operative site and either an aspiration or irrigation source for fluid or soft tissue removal and fluid delivery.

Substantial Equivalence Claim: The principles of operation and technology incorporated in the Tubing are similar to other tubing devices with the function to deliver fluids or remove soft tissue and general aspirate which the FDA has founded to be substantially equivalent to pre-amendment devices as outlined below.

Product: VCI Suction and Irrigation Tubing Sets
Manufacturer: Vital Concepts
510(k) Number: K93482
Substantial Equivalence Date: 01 February 1994

Product: Irrigation and Aspiration Tubing
Manufacturer: ARMM, Inc.
510(k) Number: K923201
Substantial Equivalence Date: Unknown

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

Product: Disposable Tubing
Manufacturer: Wells Johnson Company.
510(k) Number: Unknown
Substantial Equivalence Date: Unknown

0000000026



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

FEB 10 1998

Re: K974295
Trade Name: Byron Medical Aspiration and Infiltration/Irrigation Tubing
Regulatory Class: II
Product Code: KGZ
Dated: November 12, 1997
Received: November 14, 1997

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 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.

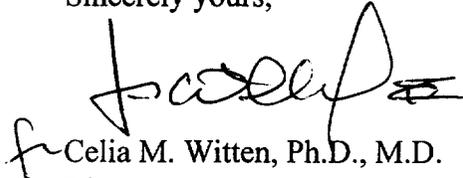
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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) 594-4595. 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" (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,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end.

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

Enclosure

510(k) Number (if known): K974295

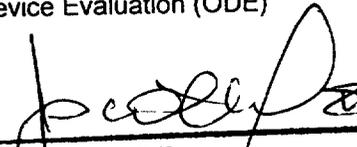
Device Name: Byron Medical Aspiration and Infiltration/Irrigation Tubing

Indications for Use:

The Tubing Indications for use are general surgical fluid, exudate, and soft tissue aspiration and general surgical 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 General Restorative Devices
510(k) Number K974295

Prescription Use
(Per 21 CFR 801.109)

Over-The Counter Use

(Optional Format 1-2-96)

0000000011