

SEP 12 1997

K973133

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: _____

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: 15 August, 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: Pressure Infusor for an I.V. bag
21 CFR § 880.5420 (1997)

Laparoscope, Gynecologic and Accessories
21 CFR § 884.1720 (1996)

Jet Lavage
21 CFR § 880.5475 (1997)

Common/Usual Name: Pressurized Irrigation/Infiltration Pump

Proprietary Name: Big Bag 3000 Pressure Infusor

Indication for Use: General surgical fluid irrigation and infiltration.

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510(k) SUMMARY (cont.)

Device Description: The principles of operation and technology incorporated in the Big Bag 3000 Pressure Infusor are equivalent to pressurized irrigation systems, which use compressed non-flammable gases within a closed bladder (inflatable cuff) to apply direct pressure externally to a bag of fluid for infusion of fluids.

Substantial Equivalence Claim: The principles of operation and technology incorporated in the Byron Medical Big Bag 3000 are similar to other irrigation devices with the function to pressurizing bags of fluid which the FDA has founded to be substantially equivalent to pre-amendment devices as outlined below.

Product: MX820-5 Pressure Infusor 500cc / MX 820-10 Pressure Infusor 1000cc
Manufacturer: Medex, Inc.
510(k) Number: K800560
Substantial Equivalence Date: 29 April 1980

Product: Nezhat-Dorsey Hydro-Dissection Universal Bag Squeezer
Manufacturer: Davol, Inc.
510(k) Number: K953574
Substantial Equivalence Date: 29 September 1995

Product: Automatic Surgical Irrigation Pump/Autocuff
Manufacturer: Alton Dean Medical, Inc./ Spartamed, Inc.
510(k) Number: K922286
Substantial Equivalence Date: Unknown

Product: Niagara Pump, 3.0 Liter High Volume
Manufacturer: Cabot Medical Systems
510(k) Number: K924530
Substantial Equivalence Date: 05 February 1993

-end of summary-



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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

Re: K973133
Trade Name: Big Bag 3000 Pressure Infusor
Regulatory Class: II
Product Code: FRN
Dated: August 15, 1997
Received: August 21, 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. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 section 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

Page 2 - Mr. Bollinger

On August 16, 1993 the Final Rule for Device Tracking was published in the Federal Register, pages 43442-43455 (copy enclosed). Be advised that under Section 519(e) of the Act as amended by the Safe Medical Devices Act of 1990, FDA has identified the above device as a device which requires tracking. Because the device is subject to tracking, you are required to adopt a method of tracking that follows the devices through the distribution chain and then identifies and follows the patients who receive them. The specific requirements of the regulation are found in 21 CFR 821 as described in the August 16, 1993 Federal Register beginning on page 43447.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in anyway represent your device or its labeling as being approved by FDA. 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), promotion, or advertising, please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. 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 at (301) 443-6597.

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

Enclosures

510(k) Number (if known): K973133

Device Name: Big Bag 3000 Pressure Infusor for General Fluid
Irrigation/Infiltration

Indications for Use:

The Big Bag 3000 Pressure Infusor indications for use are general surgical fluid irrigation and infiltration.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cucaride

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K973133

Prescription Use _____
(Per 21 CFR 801.109)

Over-The Counter Use ✓

(Optional Format 1-2-96)