

JUN 30 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: K981172

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: 31 March 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.

Suction Lipoplasty System

21 CFR § 878.5040 (05 Jan 1998)

Manual Surgical Instruments for Gen. Use
21 CFR § 878.4800 (1994)

Common/Usual Name: Aspiration and Infiltration Cannula/Needles

Proprietary Name: Lipoplasty/Liposuction Aspiration and
Tumescent Infiltration Cannulae/Needles
(Cannulae and Needles)

Indication for Use: Aesthetic Body Contouring

510(k) SUMMARY (cont.)

Device Description:

The principles of operation and technology incorporated in the **Cannulae and Needles** are equivalent to fluid, soft tissue, and exudate removal and infusion instruments generally used for aspiration and infusion, utilizing a hollow Stainless Steel tube with multiple tip, handle and attachment connectors that are in a reusable and disposable configuration.

Substantial Equivalence Claim:

The principles of operation and technology incorporated in the Cannulae and Needles are virtually exactly the same as other Aspiration and Infiltration cannulae and needle devices which are classified as Class I devices, yet with the function or intended use for aesthetic body contouring by means of aspiration and infiltration which the FDA has found to be substantially equivalent to these devices with an additional intended use of aesthetic body contouring in accordance with Section 878.5040 Suction Lipoplasty System. In terms of safety, effectiveness, and intended use, Byron Medical's Cannulae and Needles are substantially equivalent to the following commercially distributed devices:

Product: **Suction Cannulae and Needles**
Manufacturer: Byron Medical, Inc.
510(k) Number: K861878
Substantial Equivalence Date: 01 July 1986
Substantial Equivalence Letter is presented in Exhibit M.

Product: **Infusion Cannulae and Needles**
Manufacturer: Byron Medical, Inc.
510(k) Number: Class I Exempt
Substantial Equivalence Date: N/A



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 1998

Mr. Steve Bollinger
• Vice President Research and Development
Byron Medical, Inc.
3280 East Hemisphere Loop, Suite 100
Tucson, Arizona 85706

Re: K981172
Trade Name: Lipoplasty/Liposuction Aspiration and Tumescence Infusion
Regulatory Class: II
Product Code: MUU
Dated: March 31, 1998
Received: April 1, 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 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.

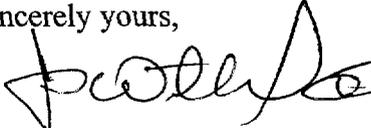
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice 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 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.

Page 2 - Mr. Steve Bollinger

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,


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): K981172

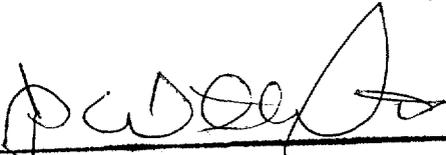
Device Name: **Lipoplasty / Liposuction Aspiration and Tumescent Infusion Cannulae and Needles**

Indications for Use:

The Aspiration and Infusion Cannulae and Needles indications for use are for Aesthetic Body Contouring.

(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 K981172

Prescription Use X
(Per 21 CFR 801.109)

Over-The Counter Use _____

(Optional Format 1-2-96)