June 8, 2021

Byron Medical
Steve Bollinger
V.P. Research And Development
3280 E. Hemisphere Loop
Suite 100
Tucson, Arizona 85706

Re: K981215
Trade/Device Name: Psi-Tec Liposuction Aspirator
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QPB

Dear Steve Bollinger:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated July 1, 1998. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Cindy Chowdhury, OHT4: Office of Surgical and Infection Control Devices, 240-402-6647, Cindy.Chowdhury@fda.hhs.gov.

Sincerely,

Cindy Chowdhury -S

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 1 1998

Mr. Steve Bollinger
Vice President, Research and Development
Byron Medical
3280 East Hemisphere Loop Suite 100
Tucson, Arizona 85708

Re: K981215
Trade Name: PSI-Tec Liposuction Aspirator
Regulatory Class: II
Product Code: MUU
Dated: April 1, 1998
Received: April 2, 1998

Dear Mr. Bollinger:

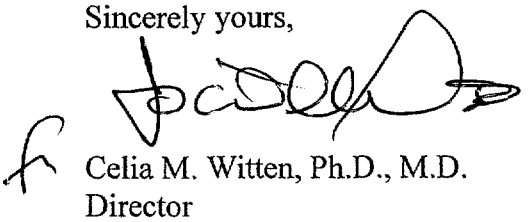
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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): K981215

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

Indications for Use:

The PSI-TEC Liposuction Aspirator(s) indications for use is 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 K981215

Prescription Use X
(Per 21 CFR 801.109

Over-The Counter Use _____

(Optional Format 1-2-96)

K981215

JUL - 1 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: K981215

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: 01 April, 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:

Suction Lipoplasty System Class II
21 CFR § 878.5040 (1998)

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

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

Common/Usual Name: Powered Suction Pump

Proprietary Name: **Psi-Tec Liposuction Aspirator**

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510(k) SUMMARY (cont.)

Indication for Use: Aesthetic Body Contouring.

Device Description: Powered Suction Pump(s)/Aspirator(s) which use an electrically (AC) driven vacuum pump generating a negative pressure for the removal of fat/adipose, soft tissue, and general 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 Liposuction Aspirator(s) are **IDENTICAL** to the following legally-marketed devices ("Predicate Devices") in terms of safety, effectiveness, with a **change of intended use:**

Product: **Psi-Tec Aspirator(s)**
Manufacturer: Byron Medical
3280 East Hemisphere Loop
Tucson, AZ 85706
510(k) Number: K980392
Substantial Equivalence Date: **05 March 1998**

-end of summary-