Tecsa Technical Services
Christine Emanuel
Regulatory Affairs Consultant
1205 De La Vina
Santa Barbara, California 93101

June 8, 2021

Re: K990602
Trade/Device Name: Richter Lipoplasty Cannulas And Accessories
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QPB

Dear Christine Emanuel:

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, 1999. 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 1999

Ms. Christine Emanuel
Regulatory Affairs Consultant
TECSA Technical Services
1205 De La Vina
Santa Barbara, California 93101

Re: K990602
Trade Name: Richter Lipoplasty Cannulas and Accessories
Regulatory Class: II
Product Code: MUU
Dated: May 8, 1999
Received: May 13, 1999

Dear Ms. Emanuel:

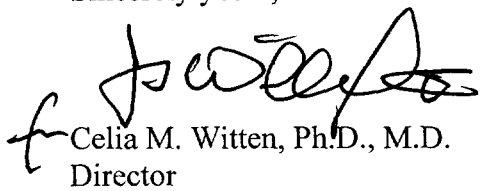
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

Include the following "Indications For Use" page that contains the applicant's name, name of the device and the intended use of the device. The information, data and labeling claims in the entire the 510(k) submission must support and agree with the "indications for use" statement.
*For a new submission, do NOT fill in the 510(k) number blank.

INDICATIONS FOR USE

Applicant: Richter Medical.

510(k) Number (if known): N/A* K990602

Device Name: Richter Lipoplasty Cannulas and Accessories

Indications For Use:

The Richter Lipoplasty Cannulas and Accessories are intended for use in aesthetic body contouring.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter _____
Per 21 CFR 801.109

(Division Sign-Off)
Division of General Restorative De...
510(k) Number K990602

JUL - 1 1999

K990602

510(k) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of SMDA and 21CFR § 807.92

Submitted by: Richter LTDA
R. Coriolano 1643
Sao Paulo
SP-Brazil, CEP 05047-001
President: Sra. Maria da Graca Richter

Fax Number: (011) 263-8636

Date Prepared: February 12, 1999

Device Name:

Proprietary Name: Richter Lipoplasty Cannulas and Accessories

Common Name: Liposuction Cannulas

Classification: Class II, 21 CFR 878.5040

Identification of Predicate Devices

- **Byron Medical, Inc.** Lipoplasty/Liposuction Aspiration and Tumescent Infiltration Cannulae/Needles, 510(k) number K981172,
- **LySonix Inc.** Aspiration Cannulas, part of the Lysonix Suction Lipoplasty System, 510(k) number K980771

Device Description:

The Richter Lipoplasty Cannulas consist of a hollow stainless steel tube, with various tip shapes, lengths and diameters. The cannulas are provided with an attached aluminum handle for aspirator connection or with aluminum couplings for syringe connection. The cannulas are available with an optional PTFE coating. The Richter Lipoplasty cannulas are provided nonsterile

Indication for Use: Cannulas for Aesthetic Body Contouring

Technological Characteristics

The design, use, and materials of the Richter Lipoplasty Cannulas and their predicate devices are equivalent, in that all these cannulas are designed to be used for aesthetic

body contouring , are fabricated out of stainless steel with optional PTFE coating, with aluminum handles, and are provided nonsterile to the user. The technological characteristics of the Richter Lipoplasty Cannulas and their predicate devices are the same. The type of tip styles and shapes are the same standard designs as those provided by the predicate devices, as are the handle and coupling styles. In summary, no new technology, materials, or use is being introduced in the design of the Richter Lipoplasty Cannulas