Biosculpture Technology, Inc.
% N.e. Devine, Jr.
Responsible Third Party Official
Entela, Inc.
3033 Madison Avenue, Se
Grand Rapids, Michigan 49548

June 8, 2021

Re: K031881
Trade/Device Name: Airbrush Liposculptor System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QPB

Dear N.e. Devine, Jr.:

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 28, 2003. 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 28 2003

Biosculpture Technology, Inc.
c/o Mr. Ned E. Devine, Jr.
Entela, Inc.
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

Re: K031881
Trade/Device Name: Airbrush™ Liposculptor System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: II
Product Code: MUU
Dated: July 15, 2003
Received: July 16, 2003

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

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

Enclosure

510(k) Number: K031881

Device Name: *Airbrush* ™ Liposculptor System

Classification Panel: MUU

Indications for Use:

The *Airbrush* ™ Liposculptor System is intended to be used for the removal of soft tissue and fluid from the body during general surgical procedures including suction lipoplasty 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)

Prescription Use X **Over-the-Counter Use** _____

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031881

JUL 2 8 2003

K031881 (p.1 of 3)

SUMMARY

Submitted By: **BioSculpture Technology, Inc.**
120 Central Park South
New York, New York 10019

Contact Person: **Robert Cucin, M.D.**

Phone: **212-977-5400**
Fax: **212-586-9529**

Proprietary Name: ***Airbrush™ Liposculptor***
Common Name: **Surgical Aspiration System**
Classification Name: **System, Suction, Lipoplasty 21 CFR§ 878.5040**

Indication for Use

The *Airbrush™* Liposculptor System is intended to be used for the removal of soft tissue and fluid from the body during general surgical procedures including suction lipoplasty for aesthetic body contouring.

Description of *Airbrush™* Liposculptor System

The *Airbrush™* Liposculptor System consists of a handheld pneumatic reciprocating hand-piece, multiple detachable and interchangeable cannulas, and the power control console (*Intellimotion™ Controller*) and connection cables. The *Airbrush™* Liposculptor System uses external air sources which the user may choose among those readily available within a hospital or clinical environment.

The pneumatic hand-piece reciprocates the inner of the two attached cannulas through an infinitely adjustable stoke length of 0-10 cm at an infinitely adjustable rate of 0-300 strokes per minute. The hand-piece is powered and controlled by the *Intellimotion™* Power Control Console.

Reciprocation of the interchangeable inner cannulas is effected by means of a releasable coupling to a carriage riding on a dual acting magnetic cylinder.

The knob on the side allows the surgeon to adjust with his/her index finger the stroke length from 0 to 10 cm. When turned to 0, the stroke knob turns reciprocation "off" and positions and locks the inner cannula at the forward most position for cannula changing, removal or manual liposuction

The trigger on the bottom, when depressed, serves to adjust the rate of reciprocation from 0-300 cpm. When released or when the instrument is set down, a spring elevates the

trigger so that reciprocation is turned "off" and the inner cannula is positioned and locked at the forward most position for cannula changing, removal or manual liposuction. The slide latch at the front of the trigger allows the trigger to be locked in a depressed position when in the posterior position and the trigger to be opened for cannula changing or removal when placed in the anterior position.

Standard suction connecting tubing is used to connect the barb at the base of the inner cannula to a conventional aspiration unit. The inlet valves at either end of the dual acting magnetic cylinder are alternately pressurized and vented by connection to air lines entering the multi-plug at the rear of the instrument. A transducer in the housing provides instantaneous feedback information as to the motion and location of the cylinder carriage at all times.

The interchangeable cannula pairs are essentially blunt-tipped hollow concentric tubes of either stainless steel or plastic. The internal diameter ranges from 2mm to 8mm and the overall length external to the instrument varies from 14 to 33 cm length. In each case one or more smaller oval apertures on the inner cannula remain aligned with a longer slot on the outer cannula during each stroke. The surgeon may vary the rate and stroke of the reciprocating action while he is actively performing liposuction. Should the surgeon set either the rate or length of stroke to zero, reciprocation is turned "off" and the device functions as a manual aspiration device.

The reciprocating action of the *Airbrush™* Liposuction simulates the manual hand motion of the surgeon. At the same time, the powered cannula minimizes surgical effort by reducing the amount of necessary hand motion.

The *Airbrush™* Liposuction System has a built-in safety feature which precludes the device being activated when cannulas are being changed or in the event hard tissue is encountered. Since inner cannula motion is by means of a magnetic linkage only, if significant resistance is encountered to inner cannula motion, the magnetic linkage will be reversibly uncoupled.

Sterility of the multiple use *Airbrush™* Liposculptor hand-piece (reusable) and connection cables (reusable) is achieved through Steam Sterilization, the disposable suction cannula and connection cables are sterilized using Gamma Radiation or Ethylene Oxide Sterilization.

Cannulas

Multiple-use inner and outer cannula is made of stainless steel. The interchangeable cannula pairs are essentially blunt-tipped hollow concentric tubes of either stainless steel or plastic. The internal diameter ranges from 2 mm to 8 mm. and the overall length external to the instrument varies from 14 to 33 cm. in length. In each case one or more

smaller apertures on the inner cannula remain aligned with a longer slot on the outer cannula during each stroke.

There are one or more holes at the tip of the inner cannulas. There is a through and through hole at the tip of the inner cannula so that the outer cannula can be rotated 180° and snapped into position to allow suctioning on the opposite side of a limb or torso by concealing one aperture and exposing the other without the necessity of changing cannulas.

Connection Cables

A single multicore cable carries all electrical and pneumatic connections from the hand piece to the power control console. Both ends are terminated by quick-connect multi-plugs..

Power Control Console

Bar graphs offer instantaneous display of the rate of reciprocation and the relative position of the inner cannula and stroke length at all times. A panel display offers a more precise digital read out of rate and stroke as well as alert conditions. Stroke may be displayed in inch or centimeter units.

The power control console receives an input of pressurized gas from any of the convenient sources available in operating room settings such as tanked nitrogen gas and uses it to power cylinder reciprocation under control of a proprietary integrated circuit which includes a digital signal processor (DSP) and analogue to digital converter (ADC). The DSP cycles four flow control valves to instantaneously vary the reciprocation rate and stroke in response to the surgeon's stroke knob and trigger settings at the hand piece. The firmness with which the carriage ends each stroke is moderately cushioned at the default factory setting but may increased or decreased in response to surgeon's preference by trained manufacturer's representatives.

Software

The software reads input from the desired stroke, rate and cushion settings and combines that with transducer input of inner cannula position to adjust appropriate cylinder pressurization and venting. When either the stroke control knob is turned to zero or the trigger released the software positions and locks the cannula in the forward position and turns the reciprocation "off" so that the cannula may be changed or removed.