510K Summary of Safety and Effectiveness
Biocellulase – SmoothShapes
December 27, 2005

1. Sponsor Name

Biocellulase, Inc.

21 Park Ave.

Newton, MA. 02458

Telephone 617 733 7077

Contact Individual: Robert Nagel

2. Device Name

Proprietary Name: SmoothShapes

Common/Usual Name: massager/shaper

Classification Name: massager, vacuum, light induced heating

3. Identification of Predicate or Legally Marketed Device

- LPG USA, Inc. - Endermology/Therapeutic Massager Vibrator - K990445
- Syneron Medical, Ltd.- VelaSmooth Shaper - K050397

4. Device Description

The SmoothShapes system consists of a main console unit and an applied part (massage head with rollers) which is connected to the main console by an umbilical. The main console unit contains the power-supply, hardware, transformers, fuses, cooling fan, mains-input connection, and the key-switch. The massage head, which is placed against the patient's skin, contains the rollers, LEDs, and laser diodes. The massage head rollers are mobilized in rotation and sliding back and forth. The patient massage is generated by the vacuum introduced to skin fold between the two rollers. The rollers in combination with the vacuum manipulate and smooth out the skin which facilitates

tissue mobilization. The laser light provides topical heating which increases tissue temperature.

5. Intended Use

The Biocellulase SmoothShapes is indicated for the relief of minor muscle aches and pain, relief of muscle spasms, temporary improvement of local blood circulation, and temporary reduction in the appearance of cellulite.

6. Comparison to Predicate Devices

The SmoothShapes is substantially equivalent to the predicates with respect to intended use and technological characteristics.

7. Nonclinical Testing

Electrical safety testing and tissue block testing (to confirm maximal skin temperature rise) is performed on the SmoothShapes device.

8. Conclusion

Based on its technological characteristics and the nonclinical testing, the Biocellulase SmoothShapes system is as safe and effective as the above-named predicate devices, for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2006

Biocellulase, Inc.
c/o Mr. Robert Nagel
President
21 Park Avenue
Newton, Massachusetts 02458

Re: K053611
Trade/Device Name: SmoothShapes
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: NUV
Dated: February 14, 2006
Received: February 14, 2006

Dear Mr. Nagel:

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 (240) 276-0115. 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 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,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053611

Device Name: SmoothShapes

Indications For Use:

The Biocellulase SmoothShapes device is indicated for the relief of minor muscle aches and pain, relief of muscle spasms, temporary improvement of local blood circulation, and temporary reduction in the appearance of cellulite.

Prescription Use _X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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, and Neurological Devices

510(k) Number K053611