Cell Bio-Systems, Inc.
Christine Emanuel
President
1205 De La Vina Street
Santa Barbara, California 93101

June 8, 2021

Re: K060089
Trade/Device Name: Tulip Disposable Cannulas
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 April 27, 2006. 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

APR 27 2006

Cell Bio-Systems, Inc.
c/o Tecsa Technical Services
Ms. Christine Emanuel
Regulatory Consultant
1205 De La Vina Street
Santa Barbara, California 93101

Re: K060089
Trade/Device Name: Tulip Disposable Cannulas
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: II
Product Code: MUU
Dated: March 22, 2006
Received: March 23, 2006

Dear Ms. Emmanuel:

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,

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

Enclosure

K060089

Indications for Use

510(k) Number (if known): K060089

Device Name: Tulip Disposable Cannulas

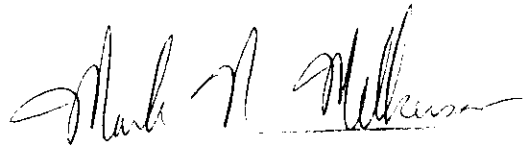
Indications for Use:

The **Tulip Disposable Cannula** is intended for use in aesthetic body contouring.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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510(k) SUMMARY

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

Submitted by:

Cell Bio-Systems, Inc.
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San Diego, CA 92108
Phone: 858-244-4800
Ed Semanik, Production
email: ed@teamcbsi.com
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APR 27 2006

Contact Person for premarket notification:
Christine Emanuel, Regulatory Consultant
1205 De La Vina Street
Santa Barbara, CA 93101
Phone: 805.963.4312
Fax: 805.564.8642
Email: cemanuel@west.net

Date Prepared: April 21, 2006

Device Name:

Proprietary Name: Tulip Disposable Cannulas

Common Name: Liposuction Cannulas

Classification: Class II, MUU, 21 CFR 878.5040

Identification of Predicate Devices

- **Byron Medical, Inc**. Lipoplasty/Liposuction Aspiration and Tumescent Infiltration Cannulae/Needles, 510(k) number K981172,
- **Richter LTDA.** Richter Lipoplasty Cannulas and Accessories, Richter LTDA, Sao Pualo, SP-Brazil, CEP 05047-001; 510(k) number K990602

Device Description:

The Tulip Disposable Cannulas are coated stainless steel cannulas designed for connection to syringes (Luer Lock® tip type or hub adaptor). The cannulas are designed to be used with a syringe aspirator or syringe re-injector. There is also an infiltrator configuration available, to administer a solution to surgery sites pre-lipoplasty. The cannulas are made of hydrophilic coated stainless steel, and are available in various diameters, lengths and tip configurations.

The Tulip Disposable Cannulas are single-use disposables, supplied sterile (e beam),

packaged in a PETG tray sealed with a labeled or pre-printed Tyvek lid.

Indication for Use: The **Tulip Disposable Cannula** is intended for use in aesthetic body contouring.

Technological Characteristics

The design, use, and materials of the Tulip Disposable Cannulas and their predicate devices are equivalent, in that all these cannulas are designed to be used for aesthetic body contouring and are fabricated out of stainless steel. Tulip Cannulas are all provided with a hydrophilic coating. The Byron cannulas provide the option of a PTFE or hydrophilic Slik-Tip coating to their users and the Richter cannulas provide the option of PTFE coating to their users. No new technology or change in indications for use have been introduced by Cell Bio-Systems in the manufacture of the Disposable Cannulas. For these reasons, Cell Bio-Systems considers the use of the **Tulip Disposable Cannulas** to be substantially equivalent to their predicate devices