DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 20 1998

Mr. Richard T. Nock
Vice President
Surgical Technology Laboratories, Inc.
1588 East 40th St.
Cleveland, Ohio 44103

Re: K983756
Trade Name: Surgiform Anatomical Malar
Regulatory Class: II
Product Code: LZK
Dated: October 16, 1998
Received: October 22, 1998

Dear Mr. Nock:

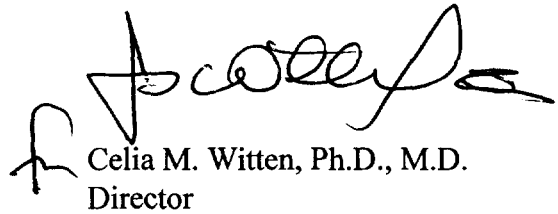
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28,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

Surgical Technology Laboratories, Inc.
1588 East 40th St. Cleveland, Ohio 44103 (216) 431-5055

K983756

510(k) Number (if known): K 983756

Device Name: Surgiform Anatomical Malar Implant

Indications for Use:

Surgiform Anatomical Malar implants can be used by surgeons in a unique surgical procedure designed to restore or enhance a patients facial appearance. The implants can be used for aesthetic or reconstructive procedures. The implants can be inserted into a "pocket" created by means of a standard intraoral surgical incision. The implants can elevate and reposition sagging skin and can also fill the hollows and depressions caused by gravity and time. The implants can also be used by surgeons to restore a patients natural appearance as a result of severe facial trauma.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983756

Prescription Use X
(Per 21 CFR 801.109)