



MAY 19 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Ashvin Desai
Manager, Regulatory Affairs
ProSurg, Inc.
2195 Trade Zone Boulevard
San Jose, California 95131

Re: K030631

Trade/Device Name: ZipperTM – Bioabsorbable/Non-absorbable Polymer Sling
and Surgical Mesh

Regulation Number: 21 CFR 878.3300

Regulation Name: Surgical mesh

Regulatory Class: II

Product Code: FTL

Dated: February 20, 2003

Received: February 28, 2003

Dear Ms. Desai:

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.

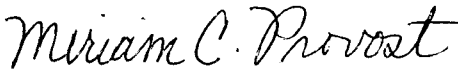
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,

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

K030631

Indications For Use:

Zippere™ - Bioabsorbable/ Non-absorbable Polymer Sling and Surgical Mesh

Zippere™ - Bioabsorbable / Non-absorbable Polymer Sling and Surgical Mesh is an implant that is intended for the treatment of urinary incontinence resulting from urethral hypermobility or ISD and for implantation to reinforce soft tissue where weakness exists in the urological, gynecological or gastroentriological anatomy. This includes, but not limited to, the following procedures: pubourethral support and bladder support, urethral and vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor and sacral colposuspension.

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030631