JUN 17 1999

K990930

ATTACHMENT D:
SUMMARY OF SAFETY AND EFFECTIVENESS
3D Anatomical™ Mesh

1. **Standards and Intended Use:**
   At present, and to the best of our knowledge, there are no standards for polypropylene surgical mesh. The **3D Anatomical™ Mesh** will conform to all future international standards for polypropylene mesh prostheses. The singular intended use of **3D Anatomical™ Mesh** is hernia repair.

2. **Manufacturing Procedures:**
   3D Anatomical™ Mesh is manufactured in a class 10,000 clean room environment in accordance with ISO 9001 and EN 46001 regulations. Full traceability will be maintained on all production lots.

3. **Prior In-Vitro Tests and Clinical Experience:**
   3D Anatomical™ Mesh is CE marked (no. 0413)
   In-vitro testing of the **3D Anatomical™ Mesh** was conducted by Institut Textile de France, Ecully, France and produced the following results:
   a) weave density: $0.91 g/cm^3$
   b) tensile strength: **3D Anatomical™ Mesh** must exceed 40 daN (greater than 50% elongation prior to rupture)
   c) burst strength: **3D Anatomical™ Mesh** must exceed 500 kPa
   Clinical experience of **3D Anatomical™ Mesh** began internationally in 1994 and now includes thousands of mesh implants.

   In-vitro chemical testing was performed by Laboratoire de Rheologie des Matieres Plastiques, St. Etienne, France and concluded:
   a) through comparative infrared spectrometry, a lot batch of 3D Anatomical polypropylene was positively compared to a reference polypropylene that was specified to be a monofilament, 100% polypropylene homopolymer.
   b) Through comparative thermal analysis, both the lot batch of 3D Anatomical polypropylene and the reference polypropylene sample exhibited fusion temperatures between 160°C and 175°C and both exhibited crystallization above 60%.

4. **Contact Information:** Inquiries should be directed to:

Santerra Medical Technology, Inc.
5451 Hilltop Avenue
Lake Elmo, MN 55042-9539
Tel: (651) 704-9160
Fax: (651) 704-9191

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 1999

Mr. David P. Lang
Chief Executive Officer
Santerra Medical Technology, Inc.
5451 Hilltop Avenue
Lake Elmo, Minnesota 55042

Re: K990930
Trade Name: 3D Anatomical™ Mesh
Regulatory Class: II
Product Code: FTL
Dated: March 16, 1999
Received: March 19, 1999

Dear Mr. Lang:

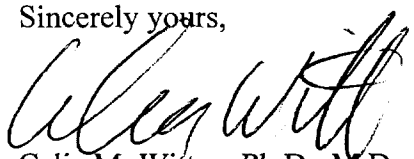
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirement, 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/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

K990930

510(k) Number (if known): _____

Device Name: **3D Anatomical™ Mesh**

Indications For Use:

The indications for use of **3D Anatomical™ Mesh** are:
1) inguinal hernia repair
2) ventral abdominal wall hernia repair

(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 Devices
510(k) Number K990930

Prescription Use X
(21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)