 MAY 20 1998

K974540

J. 510(K) SUMMARY

Submitted By:

Robert J. Morff, Ph.D., P.E.
Associate Director, Medical Technology
Sentron Medical, Incorporated
4445 Lake Forest Drive, Suite 600
Cincinnati, Ohio 45242
(513) 563-3254
November 26, 1997

Device:

Trade Name	SIS Hernia Repair Device
Common/Usual Name:	Hernia Patch, Tissue Patch, Surgical Mesh
Proposed Classification:	Surgical Mesh 21 CFR Part 878.3300 (uoFTL) Class II

Predicate Devices:

The SIS Hernia Repair Device is similar to predicate surgical meshes in terms of indications for use, and technological characteristics.

Device Description:

The SIS Hernia Repair Device is intended to be used for reconstructing and supporting soft tissues such as fo the repair of a hernia or body wall defect. The device is supplied sterile and is intended for one-time use. The material comprising the device has undergone appropriate biocompatibility and performance testing that provides reasonable assurance of safety and efficacy for its intended use.

Substantial Equivalence:

The device will be manufactured according to specified process controls and a Quality Assurance Program. The device will be packaged and sterilized using validated sterilization procedures. This device is similar with respect to indications for use and technology to predicate devices in terms of section 510(k) substantial equivalency.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 1998

Robert J. Morff, Ph.D., P.E.
Associate Director, Medical Technology
Senmed Medical Ventures
Sentron Medical, Incorporated
4445 Lake Forest Drive, Suite 600
Cincinnati, Ohio 45242

Re: K974540
Trade Name: SIS Hernia Repair Device
Regulatory Class: II
Product Code: FTL
Dated: April 2, 1998
Received: April 3, 1998

Dear Dr. Morff:

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

510(k) Number (if known): K974540

Device Name: SIS Hernia Repair Device

Indications For Use:

The SIS Hernia Repair Device is intended to be implanted to reinforce soft tissues where weakness exists. Indications for use include the repair of a hernia or body wall defect. The device is intended for one-time use.

(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 K974540

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____