SEP 2 4 2004

K042412

Attachment 4

510(k) Summary

Modified SPACEMAKER* System

United States Surgical
150 Glover Avenue
Norwalk, CT 06856
USA

DEVICE DESCRIPTION

The Modified SPACEMAKER* System consists of a balloon dissector and trocar which are used in conjunction to provide a port of access and tissue separation during laparoscopic surgery.

CLASSIFICATION NAME

Balloon Dissectors/ Balloon Trocars

INDICATIONS FOR USE

SPACEMAKER* Structural Balloon Trocar

The **SPACEMAKER*** Structural Balloon Trocar is primarily indicated for patients undergoing laparoscopic surgical procedures requiring a sealed port of access and/or tissue retraction. This is also indicated in patients undergoing laparoscopic surgery requiring a sealed port of access and/or tissue separation in extraperitoneal procedures, such as in hernia repair, lymphadenectomy or bladder neck suspension procedures.

SPACEMAKER* Blunt Tip Trocar

The SPACEMAKER* Blunt Tip Trocar is intended for use in establishing a port of access for insertion of endoscopic instruments into the abdominal cavity or extraperitoneal space in abdominal and extraperitoneal surgery.

SPACEMAKER* Dissection Balloon

The SPACEMAKER* Dissection Balloon is primarily indicated for patients undergoing laparoscopic surgery requiring tissue separation of the extraperitoneal space.

MATERIALS:

All material components of the Modified SPACEMAKER* System comply with ISO Standard #10993-1.

PREDICATE DEVICES

Auto Suture* Dissection Balloon
Auto Suture* Blunt Tip Trocar
Auto Suture* Structural Balloon Trocar

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 4 2004

Ms. Reneé Alfano
Associate, Regulatory Affairs
United States Surgical
150 Glover Avenue
Norwalk, Connecticut 06856

Re: K042412
Trade/Device Name: Modified SPACEMAKER System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: September 2, 2004
Received: September 7, 2004

Dear Ms. Alfano:

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. 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,

Miriam C. Provost

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

Attachment 2

Indications for Use Statement

Device Name

Modified SPACEMAKER* System

Indications For Use

The Modified SPACEMAKER* System:

SPACEMAKER* Structural Balloon Trocar
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SPACEMAKER* Dissection Balloon
The SPACEMAKER* Dissection Balloon is primarily indicated for patients undergoing laparoscopic surgery requiring tissue separation of the extraperitoneal space.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-The-Counter Use:_____
(Per 21 CFR 801.109)

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

510(k) Number K042412