K973046

Appendix 4

510(k) Summary

JAN 16 1998

1. **Contact Person:** Cathleen Mantor
General Surgical Innovations, Inc.
10460 Bubb Road
Cupertino, CA 95014
(408) 863-2531 863-1100 (fax)

2. **Date Summary Prepared :** August 8, 1997

3. **Trade Name(s):**

Spacemaker® Surgical Balloon Dissector with and without Cannula
Spacemaker® II Surgical Balloon Dissector with and without Cannula
Spacemaker® Serial Surgical Balloon Dissector w/ or w/o Cannula & w/ or w/o Visualization

4. **Common Name**

Surgical Balloon Dissector

5. **Predicate devices**

K926010 Surgical Dissector with Cannula
K944418 Spacemaker® and Spacemaker II Surgical Balloon Dissector and Cannula
K951878 Spacemaker® and Spacemaker® II Surgical Balloon Dissector with and without a Cannula, Class II
K952278 Reusable Spacemaker® Surgical Balloon Dissector with Cannula
K962702 Spacemaker® Serial Surgical Balloon Dissector with or without Cannula and with or without Visualization
K953377 Tapered Tip Balloon Dissection Cannula
K935426 Preperitoneal Distention Balloon System
K946002 Longitudinal Dissection Balloon System
K954174 Duo Balloon System (1and 2)
K964171 VasosView Balloon Dissection System

6. **Device Description**

The Spacemaker® Surgical Balloon Dissector devices are handheld, manually manipulated surgical balloon dissectors. The devices can be supplied with either a solid center rod or a hollow center rod. The hollow center rod allows for the insertion of an endoscopic visualization accessory, if desired. The devices can be supplied with or without a cannula. The cannula

provides access for operative and diagnostic instrumentation for the duration of the surgical procedure.

This submission seeks to gain clearance for the Spacemaker® Surgical Balloon Dissectors with all of the specific indications for use that have been delineated in previous submissions.

7. Intended Use

The device is indicated for any area of the body where it is necessary to separate the layers of connective tissue for surgical access. The intended use of the Spacemaker® Surgical Balloon Dissectors is to create an operative space by dissecting layers of connective tissue along natural tissue planes of separation of the extraperitoneal (including preperitoneal and retroperitoneal), or subcutaneous extremity or thoracic space.

The indications for use include dissection of tissue for the following surgical procedures: endoscopic; laparoscopic; general surgery; plastic and reconstructive surgery, including aesthetic surgery; vascular surgery for the exposure of superficial vessels of the upper and/or lower extremities (no deep structure would be targeted), including the saphenous vein and femoral vessels; thoracoscopic procedures involving exposure and dissection of structures external to the parietal pleura, including nerves, blood vessels and other tissues of the chest wall; procedures in the extraperitoneal space involving dissection of tissue layers allowing exposure of structures including: adrenals, bone, spine, lymph nodes, and kidneys.

Examples of specific surgical procedures the Spacemaker® Surgical Balloon Dissectors may be used to facilitate tissue dissection include: fascial layers between the skin and peritoneum, hernia repair, varicocele dissection, sympathectomy, lymph node dissection, urethropexy, subfascial perforator vein ligation, access to the saphenous vein and femoral vessels, retroperitoneal access to the anterior spine, access for long bone plating.

The cannula portion of the device is intended to provide access for surgical and diagnostic instruments for the duration of the operative procedure.

8. Comparison to Predicate Devices

Substantial equivalence is based on the fact that all of the Spacemaker® Surgical Balloon Dissectors have the same principle of operation as the predicate devices (there are no changes to any of the Spacemaker® devices). There are no new indications for use. All of the indications for

use have been included in one or more of the predicate device submissions and including these indications for use in all of the Spacemaker® Surgical Balloon Dissectors labeling does not raise different questions regarding safety or efficacy or have any impact on safety and efficacy of the Spacemaker® Surgical Balloon Dissectors compared to the predicate devices. Therefore, it can be concluded that the Spacemaker® Surgical Balloon Dissectors with the inclusion of the indications for use (from the predicate devices) are substantially equivalent to the predicate devices.

9. Testing in Support of Substantial Equivalence Determination

No functional bench testing was performed for this submission because no tests were necessary to substantiate the safety, performance or substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 1998

Ms. Cathleen Mantor
Regulatory Affairs/Quality Assurance Manager
General Surgical Innovations
10460 Bubb Road
Cupertino, California 95014

Re: K973046
Trade Name: Spacemaker® Surgical Balloon Dissector, Spacemaker® II Surgical Balloon Dissector
Regulatory Class: II
Product Code: GCJ
Dated: October 31, 1997
Received: November 5, 1997

Dear Ms. Mantor:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification

submissions 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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,

for 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

8.1 Statement of Indications for Use

510(k) Number (If Known): 973046

Device Name:

Spacemaker® Surgical Balloon Dissector with and without Cannula
Spacemaker® II Surgical Balloon Dissector with and without Cannula
Spacemaker® Serial Surgical Balloon Dissector w/ or w/o Cannula & w/ or w/o Visualization

Indications For Use:

The device is indicated for any area of the body where it is necessary to separate the layers of connective tissue for surgical access. The intended use of the Spacemaker® Surgical Balloon Dissectors is to create a operative space by dissecting layers of connective tissue along natural tissue planes of separation of the extraperitoneal (including preperitoneal and retroperitoneal), or subcutaneous extremity or thoracic space.

The indications for use include dissection of tissue for the following surgical procedures: endoscopic; laparoscopic; general surgery; plastic and reconstructive surgery, including aesthetic surgery; vascular surgery for the exposure of superficial vessels of the upper and/or lower extremities (no deep structure would be targeted), including the saphenous vein and femoral vessels; thoracoscopic procedures involving exposure and dissection of structures external to the parietal pleura, including nerves, blood vessels and other tissues of the chest wall; procedures in the extraperitoneal space involving dissection of tissue layers allowing exposure of structures including: adrenals, bone, spine, lymph nodes, and kidneys.

Examples of specific surgical procedures the Spacemaker® Surgical Balloon Dissectors may be used to facilitate tissue dissection include: fascial layers between the skin and peritoneum, hernia repair, varicocele dissection, sympathectomy, lymph node dissection, urethropexy, subfascial perforator vein ligation, access to the saphenous vein and femoral vessels, retroperitoneal access to the anterior spine, access for long bone plating.

The cannula portion of the device is intended to provide access for surgical and diagnostic instruments for the duration of the operative procedure.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign Off)

Division of General Restorative Devices

510(k) Number K973046