

## SECTION 6

## 510(k) SUMMARY (21 CFR 807.92)

K 9815 98

1. **Device Name:** Hernia Mesh Stabilizer  
**Classification Name:** Laparoscopic Accessory
2. **Predicate Device:** GraNee Needle System for Hernia Repair. During Laparoscopic Hernia Repair, the GraNee Needle enters the abdominal wall through a separate incision and captures the sutures attached to the surgical mesh, withdraws the sutures and either permanently attaches the mesh in place with the sutures or holds the mesh against the abdominal wall for permanent attachment with staples.
3. **Device Description:** Stylet with 16 gauge Cannula, for insertion through a separate incision into the abdominal cavity, in Laparoscopic Hernia Repair, to capture and temporarily hold, with spring retraction, the surgical mesh against the abdominal wall for permanent attachment by stapling. On completion of stapling, the stylet and cannula are advanced to release the mesh, enclose the hook within the cannula and safely remove the Hernia Mesh Stabilizer from the surgical site.
4. **Intended Use:** Temporary mesh fixation to the inner surface of the abdominal wall to facilitate the permanent placement, by stapling, of the mesh when used in the standard fixation technique for Laparoscopic Hernia Repair.
5. **Comparative Summary:** Both the Hernia Mesh Stabilizer and the predicate device enter the surgical site through separate incisions to capture and hold surgical mesh against the abdominal wall prior to permanent stapling of the mesh over the herniated area. Both devices have internal body contact surfaces made of stainless steel and are provided to the user packaged sterile, for single use.

**Section 6 (continued)**

**Summary Submitted by:**

**John K. Belknap  
President  
Medivices, Inc.  
1740 Amherst Street  
Buffalo, NY 14214  
Telephone: 716-835-5888  
Fax: 716-862-0483  
April 27, 1998**



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 1 1998

Medivices, Inc.  
c/o Thomas L. Parker  
29 Lancaster Lane  
Orchard Park, New York 14127

Re: K981598  
Trade Name: Hernia Mesh Stabilizer  
Regulatory Class: II  
Product Code: GCJ  
Dated: April 30, 1998  
Received: May 4, 1998

Dear Mr. Parker:

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.

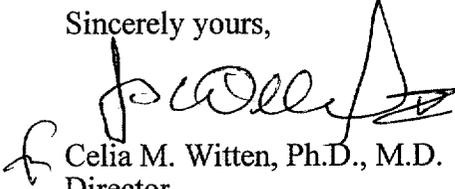
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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,



A handwritten signature in black ink, appearing to read "C. Witten", is written over the typed name. The signature is stylized and includes a large, sweeping flourish at the end.

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

SECTION 5

INDICATIONS FOR USE

HERNIA MESH STABILIZER

K 981598

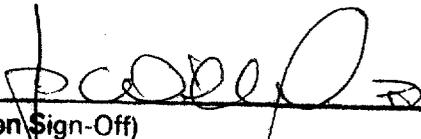
Temporary mesh fixation to the inner surface of the abdominal wall to facilitate the permanent placement, by stapling, of the mesh when used in the standard fixation technique for Laparoscopic Hernia Repair.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

Over-The-Counter Use

  
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(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K981598