K960101

ISLAND BIOSURGICAL, INC.

DEC 16 1996

Feb 21, 1996

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Blvd
Rockville, MD 20850

Re: 510 (k) Summary of Safety and Effectiveness

Island Biosurgical Establishment
Registration No.: 9009464
K960101

Attention: Document Mail Clerk

The following is a summary of the information submitted in the complete 510(k) for the Island Biosurgical bolster.

Trade Name: Island Biosurgical Bolster
Common Name: Surgical Bolster
Classification Name: Mesh, Surgical, Polymeric

Substantial Equivalence: Marlex polypropylene mesh

Description: A preformed surgical mesh device with sutures woven along the edges.

Intended use: Supporting the endopelvic fascia in bladder neck surgery for stress incontinence.

Technological characteristics: No differences from the legally marketed polypropylene mesh.

1-800-858-5359
18 Meadow Lane
Mercer Island, WA
98040-5340
FAX 206/656-5002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 28 2012

Hunter A. McKay, M.D.
President
Island Biosurgical, Inc.
18 Meadow Lane
MERCER ISLAND WA 98040

Re: K960101
Trade/Device Name: Island Biosurgical Bolster
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: November 5, 1996
Received: November 13, 1996

Dear Dr. McKay:

This letter corrects our substantially equivalent letter of December 16, 1996.

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 (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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ISLAND BIOSURGICAL, INC.

November 5, 1996

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Blvd Rockville, MD 20850

Re: 510 (k) Response to inquiry of Oct 30, 1996
Island Biosurgical Establishment Registration No.: 9009464
K960101

Attention: Document Mail Clerk

The following is a response to your recent inquiry (copy attached for reference):

INDICATION FOR USE

The Island Biosurgical Bolster is indicated for correction of pelvic floor relaxation or herniation at the bladder neck level.

Sincerely yours,

Hunter A. McKay, M.D.
President

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K960101

Prescription Use X
(Per 21 CFR 801.109)

Over-the-Counter Use

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Mercer Island, WA
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