

SEP 8 1998



ISLAND BIOSURGICAL, INC.

K982042

Bladder Neck Suspension Bolster  
Island Biosurgical, Inc.  
510(k) Notification

510(k) SUMMARY

Contact Person: Hunter A. McKay, M.D.  
Date: June 4, 1998  
Trade Name: Island Biosurgical Bladder Neck  
Suspension Bolster #2  
Common Name: Bladder Neck Suspension Bolster  
Classification Name: None available  
Predicate device: Island Biosurgical Bladder Neck  
Suspension Bolster  
Substantial Equivalence: Island Biosurgical Bladder  
Neck Suspension Bolster  
Description: A surgically implantable polypropylene  
mesh bolster with monofilament sutures.  
Intended use: The Island Biosurgical Bladder Neck  
Suspension Bolster is to be used by operating  
pelvic surgeons to surgically correct female  
stress urinary incontinence due to pelvic  
relaxation.  
Technological characteristics: This implantable  
bolster is composed of polypropylene mesh and  
monofilament suture material.  
Performance testing: Performance testing was not  
included in this 510(k).

Ref: \A\P\FDA\Bolster\980604\Summary.022



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

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

SEP 28 2012

Re: K982042  
Trade/Device Name: Island Biosurgical, Inc. Bladder Neck Suspension Bolster  
Regulation Number: 21 CFR 878.3300  
Regulation Name: Surgical mesh  
Regulatory Class: II  
Product Code: OTN  
Dated: June 4, 1998  
Received: June 10, 1998

Dear Dr. McKay:

This letter corrects our substantially equivalent letter of September 8, 1998.

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.

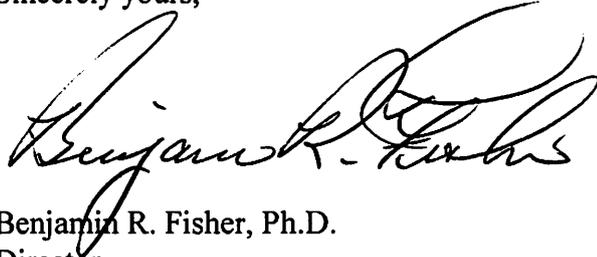
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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,

A handwritten signature in black ink, appearing to read "Benjamin R. Fisher". The signature is fluid and cursive, with a large initial "B" and "F".

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

