K053492 (pg 1 of 1)

510(k) Summary

APR 12 2007

Trade Name: Meniscal Fixation Device

Name of Sponsor: BioDuct, LLC
3201 Stellhorn Road
Fort Wayne, Indiana, 46815.

510(k) Contact: Herb Schwartz, Ph.D.
Telephone: (260) 407-6468
FAX: (260) 492-0452

Common Name: Biodegradable soft tissue fixation device

Classification: 21 CFR 888.3030 - Single/multiple component metallic bone fixation appliances and accessories, Class II

Product Code: 87 MAI

Predicate Devices: K002406 – DePuy Mitek RapidLoc™ Meniscal Repair System
K991715 – Linvatec BioStinger™ Meniscal Fixation System
K980681 – Innovasive Devices Meniscal Screw
K955768 – Bionx Biofix® Meniscus Arrow
K003070 – Ethicon Ethibond Excel Suture
K983577 - Arthrex Meniscal Dart System

Indications for use:
BioDuct's Meniscal Fixation Device is intended for fixation of longitudinal vertical meniscus (bucket handle) lesions located in the vascularized (red-white) zone of the meniscus when used with suture.

Device Description:
BioDuct's Meniscal Fixation Device is an arthroscopically implanted, cannulated, bioabsorbable (PLA) device used with suture, and is available in sizes ranging from 5 to 14 mm long. The Meniscal Fixation Device is designed to be placed between the synovium and a lesion located in less well vascularized (red-white) areas of the meniscus. Mechanical testing results indicate that the Meniscal Fixation Device, when used with suture (i.e. 5-0 Ethilon), improves the 3 month fixation strength of the lesion compared to trephination and suture (i.e. 5-0 Ethilon) alone as shown in the canine model.

Substantial Equivalence:
Based on similarities in indications, design and materials and the results of comparative testing, BioDuct's Meniscal Fixation Device is substantially equivalent to other biodegradable soft tissue fixation devices, including the predicates listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

BioDuct, LLC
c/o Herb Schwartz, Ph.D.
President
3201 Stellhorn Road
Fort Wayne, Indiana 46815

APR 12 2007

Re: K053492
Trade/Device Name: BioDuct's Meniscal Fixation Device
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI
Dated: February 20, 2007
Received: February 22, 2007

Dear Dr. Schwartz:

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.

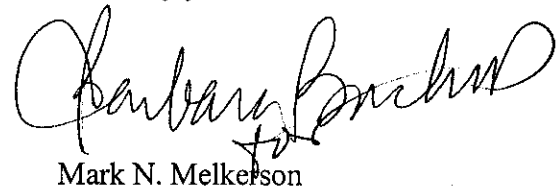
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053492

Device Name: BioDuct's Meniscal Fixation Device

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053492