

K981340

JUN 22 1998

510(K) SUMMARY

1. SUBMITTER:

Innovasive Devices, Inc.
734 Forest St.
Marlborough, MA 01752
Telephone: 508-460-8229

Contact: Eric Bannon, Vice President of Regulatory Affairs, Quality Assurance
Date Prepared: April 10, 1998

2. DEVICE:

Innovasive Meniscal Dart
Classification Name: Bioabsorbable Orthopedic Fixation Device
Trade Name: Innovasive Devices Meniscal Dart

3. PREDICATE DEVICE:

The predicate devices used to determine substantial equivalence for the Innovasive Devices Meniscal Dart was the Biofix Arrow marketed by Bioscience Ltd, Malvern, PA

4. DEVICE DESCRIPTION:

The Meniscal Dart is a device fabricated from L-PLA which is intended for meniscal repair. The device consists of a molded device with a back tab and barbs along its length. The device is inserted into the meniscus with the aid of an inserter instrument. Additional instruments include calibrators to measure the meniscus, rasps and setting tools. The device will be offered in 3 sizes, 10, 11 and 13mm.

5. INTENDED USE:

The intended use of the Meniscal Dart is intended for use in the arthroscopic fixation of longitudinal vertical meniscus lesions (bucket handle lesions) located in the vascularized area of the meniscus (red-red and red-white areas).

6. COMPARISON OF CHARACTERISTICS:

The Meniscal Dart is fabricated from L-PLA, the same material as the Biofix Arrow. The design is also similar with the Dart using barbs along its length to hold in the meniscal tissue. The insertion technique is also similar between the Dart and

Arrow in that the device is placed across the tear and the device used to approximate the tear. The Arrow does use a needle and cannula to place the device where the Dart does not.

The indications for use of the two devices are identical.

7. PERFORMANCE DATA:

The following performance data was provided in support of the substantial equivalence determination:

1. **Bench Testing:** Comparison of the fatigue strength of the Meniscal Dart in vitro compared to the predicate device. In addition, the performance of the device was assessed under constant load as was the weight loss and intrinsic viscosity.
2. **Animal Testing:** The testing demonstrated the efficacy of the Innovative Meniscal Dart and confirmed that the device functions adequately to meet its intended use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Eric Bannon
Vice President of Regulatory Affairs
and Quality Assurance
Innovasive Devices, Inc.
734 Forest Street
Marlborough, Massachusetts 01752

Re: K981340
Innovasive Device Meniscal Dart Repair System
Regulatory Class: II
Product Codes: MAI and GAM
Dated: April 10, 1998
Received: April 13, 1998

Dear Mr. Bannon:

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.

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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.

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) 594-4659. 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,



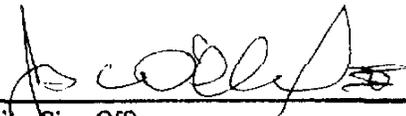
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Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

The intended use of the Meniscal Screw is intended for use in the arthroscopic fixation of longitudinal vertical meniscus lesions (bucket handle lesions) located in the vascularized area of the meniscus (red-red and red-white areas).



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K981340

Prescription Use X
(Per 21 CFR 801.109)