JUL - 1 1999

INNOVASIVE DEVICES

K990454

510(K) SUMMARY

1. SUBMITTER:

Innovasive Devices, Inc.
734 Forest St.
Marlborough, MA 01752
Telephone: 508-460-8229
Fax: 508-460-6661

Contact: Kathleen Morahan, Regulatory Affairs Specialist
Date Prepared: February 11, 1999

2. DEVICE:

Trade Name: Innovasive Bio-Interference Screw

Common Name: Interference Screw

Classification Name: Not Classified

3. PREDICATE DEVICE:

(1) Arthrex Bio-Interference Screw - K971358

4. DEVICE DESCRIPTION:

The Bio-Interference Screw is a biodegradable interference screw intended for interference fit fixation of soft tissue grafts or bone-tendon-bone grafts during cruciate ligament reconstruction surgeries of the knee. The device is offered in varying diameters and lengths.

5. INTENDED USE:

The proposed Bio-Interference Screw is intended for the fixation of soft tissue grafts or bone-tendon-bone grafts during cruciate ligament reconstruction surgeries of the knee.

6. COMPARISON OF CHARACTERISTICS:

The design of Innovasive's proposed Bio-Interference Screw is very similar to the predicate device: both devices are cannulated, threaded, tapered, and are offered in varying diameters and lengths. Innovasive's proposed Bio-Interference Screw and Arthrex's Bio-Interference Screw are also molded from the same material: Poly-L-Lactide (L-PLA).

The indication being requested for the proposed Bio-Interference Screw is already cleared for Arthrex's Bio-Interference Screw.

7. PERFORMANCE DATA:

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

Bone Model Testing: the ultimate holding strength of the proposed Bio-Interference Screw was compared to the currently marketed Arthrex Bio-Interference Screw. The testing demonstrates substantially equivalent performance between the two devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Kathleen Morahan
Regulatory Affairs Specialist
Innovasive Devices, Inc.
734 Forest St.
Marlborough, Massachusetts 01752

Re: K990454
Trade Name: Innovasive Bio-Interference Screw
Regulatory Class: II
Product Code: HWC
Dated: May 5, 1999
Received: May 6, 1999

Dear Ms. Morahan:

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.

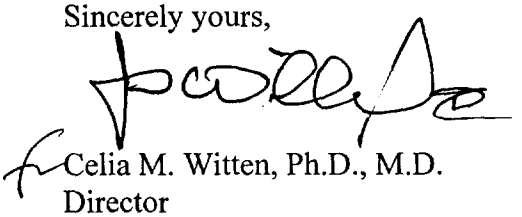
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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 at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



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

CONFIDENTIAL

510(k) Number (if known): K990454

Device Name: Bio-Interference Screw

Indications for Use:

The Bio-Interference Screw is intended for fixation of soft tissue grafts or bone-tendon-bone grafts during cruciate ligament reconstruction surgeries of the knee.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990454