

JAN 28 1999

K 983560
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: October 8, 1998

2. DEVICE:

Innovasive Devices Intratunnel Tibial Fixation Fastener
Classification Name: single/multiple component bone fixation appliances and accessories.
Trade Name: Innovasive Devices Intratunnel Tibial Fixation Fastener

3. PREDICATE DEVICE:

The predicate devices used to determine substantial equivalence for the Innovasive Devices Intratunnel Tibial Fixation Fastener was the RCI Screw marketed by Smith & Nephew DonJoy, Carlsbad, CA

4. DEVICE DESCRIPTION:

The Innovasive Intratunnel Tibial Fixation Fastener consists of two components, an Expansion Sheath, and Expansion Screw. Also included with the system is the instrumentation to place the devices and establish the tunnel. The device functions by establishing the tibia-femoral tunnel and placing the Expansion Sheath into the tibial tunnel. This is followed by screwing an Expansion Screw into the Sheath, expanding the Sheath which compresses the graft against the tunnel and creating fixation.

5. INTENDED USE:

The intended use of the Intratunnel Tibial Fixation Fastener is for fixation of soft tissue grafts during cruciate ligament reconstruction surgeries of the knee.

6. COMPARISON OF CHARACTERISTICS:

The Innovasive Intratunnel Tibial Fixation Fastener consists of two components: the Expansion Sheath, fabricated from High Density Polyethylene, and the

Expansion Screw, fabricated from either Acetal, or titanium. The device functions by establishing the tibia-femoral tunnel and placing the Expansion Sheath into the tibial tunnel. This is followed by screwing an Expansion Screw into the Sheath, expanding the Sheath which compresses the graft against the tunnel and creating fixation.

The RCI Screw is fabricated from titanium and provides fixation through interface of the screw threads to the soft tissue graft.

The indications for use of the two devices are the same.

7. PERFORMANCE DATA:

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

1. Bench Testing: Comparison of the static holding strength of the Intratunnel Tibial Fixation Fastener compared to the predicate device in a porcine model.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K983560
Trade Name: Intratunnel Tibial Fixation Fastener
Regulatory Class: II
Product Code: MBI
Dated: January 19, 1999
Received: January 20, 1999

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.

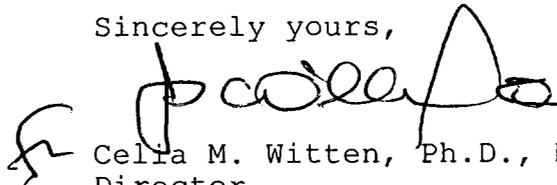
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

A handwritten signature in black ink, appearing to read "C. Witten". The signature is written in a cursive style with a large, prominent initial "C".

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

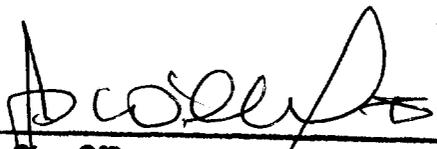
Enclosure

INDICATIONS FOR USE

The intended use of the Intratunnel Tibial Fixation Fastener is for fixation of soft tissue grafts during cruciate ligament reconstruction surgeries of the knee.

Prescription Use _____
(Per 21 CFR 801.109)

X



(Division Sign-Off)
Division of General Restorative Devices

510(k) Number _____

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