

OCT 13 1998

510(K) SUMMARY**1. SUBMITTER:**

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

Contact: Kathleen Morahan, Regulatory Affairs Specialist
Date Prepared: August 28, 1998

2. DEVICE:

Innovasive Tibial Fastener
Classification Name: Single/multiple component bone fixation appliances and accessories.

Trade Name: Innovasive Devices Tibial Fastener

3. PREDICATE DEVICE:

The predicate devices used to determine substantial equivalence for Innovasive's Tibial Fastener are (1) the LinX Tibial Ligament Fastener, and (2) the Soft Tissue Screw & Washer System, both marketed by Innovasive Devices, Marlborough, MA.

4. DEVICE DESCRIPTION:

Innovasive's proposed Tibial Fastener utilizes a **central pin** placed inside an **outer sleeve**.

The central pin is threaded its entire length, resembling a "screw". The pin is cannulated in a hex shape to fit a *Hex Driver* for insertion into the outer sleeve. The pin is designed to lock into the central ID of the outer sleeve.

The outer sleeve has a threaded central ID to accept the pin component, and an angled plate designed to lay flush against the tibia and prevent the device from pulling through the tibial tunnel. The angled plate will be offered in three angles: 40°, 45°, and 50° to accommodate varying tibial tunnel angles. The outer sleeve is manually placed in the tibial tunnel, and the graft passed through the sleeve's central ID. A *Sizer* is used to determine the appropriate pin diameter and length by insertion into the sleeve between the graft strands. The pin is then inserted into the central ID, and locks into the sleeve. Any excess graft ends may be removed.

The proposed Tibial Fastener outer sleeve and central pin will be offered in various sizes to accommodate varying graft and tibial tunnel sizes.

5. INTENDED USE:

The Tibial Fastener is intended for use in bone fixation of ligament and tendon grafts during cruciate ligament reconstruction surgeries.

6. COMPARISON OF CHARACTERISTICS:

The Innovative Tibial Fastener utilizes the same basic design as the currently cleared LinX Tibial Ligament Fastener (K990491): a **central pin** placed inside an **outer sleeve**.

The proposed Tibial Fastener central pin material is *identical* to that of the currently cleared LinX Tibial Ligament Fastener central pin: molded Delrin (Dupont 500P or 100P NC010). The outer sleeve of the proposed Tibial Fastener is also molded from Delrin (Dupont 500P or 100P NC010). The predicate LinX Tibial Ligament Fastener outer sleeve is molded from high density polyethylene (Dow Chemical HD 8354N).

The central pin of the currently cleared device consists of a distal ribbed section designed to lock into the sleeve, and a proximal section with an eyelet to which the graft is threaded through and sutured to. The central pin of the proposed device is threaded its entire length, resembling a screw, and is cannulated in a hex shape to fit a *Hex Driver* that is used to insert the pin into the outer sleeve. The proposed pin will be offered in varying diameters, 6mm-11mm, and lengths, ranging from 20mm-40mm.

The existing LinX Tibial Ligament Fastener outer sleeve ID is smooth, whereas the proposed Tibial Fastener outer sleeve ID is threaded to increase the pin/sleeve interference. To accommodate different tunnel angles that are drilled per the surgeon's choice, the sleeve will be offered with an angled plate at 40° and 50°, in addition to the predicate LinX Tibial Ligament Fastener outer sleeve design of 45°. The proposed Tibial Fastener sleeve will be offered in three sizes: Small (7mm-8mm grafts), Medium (9mm-10mm grafts), and Large (11mm-12mm grafts). The predicate outer sleeve is offered in one size. The overall length of the sleeve is *identical* to the currently cleared LinX Tibial Ligament Fastener.

The method of graft fixation for the proposed Tibial Fastener differs from the existing LinX Tibial Ligament Fastener in that the graft is not threaded through and sutured to the pin, but threaded through the sleeve. The sleeve is manually placed in the tibial tunnel and the pin is inserted into the sleeve acting as a shim to retain the ligament. Any excess graft is removed. This method of graft fixation is *identical* to Innovative's Soft Tissue Screw & Washer System (K962194), except

this currently marketed system does not utilize a sleeve, and a Washer is used to anchor the free ends of the graft to the tibia.

7. PERFORMANCE DATA:

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

1. Mechanical Testing: the ultimate holding strength of the proposed Tibial Fastener in human cadaver was compared to the predicate devices. As expected, the proposed Tibial Fastener holding strength was found to be substantially equivalent to that of the LinX Tibial Ligament Fastener, and the Soft Tissue Screw & Washer System.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K983056
Trade Name: Innovasive Tibial Fastener
Regulatory Class: II
Product Codes: MBI and JDW
Dated: August 28, 1998
Received: September 1, 1998

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.

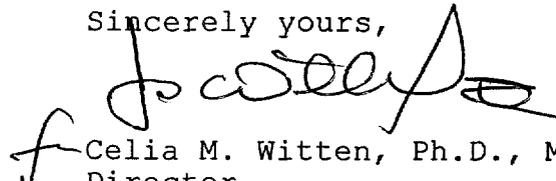
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

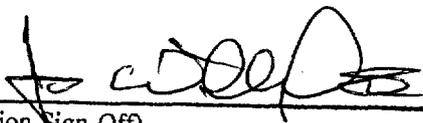

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE
Tibial Fastener

The Tibial Fastener is intended for use in the fixation of ligament and tendon grafts in cruciate ligament reconstruction surgeries of the knee.

Prescription Use X
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number 12983056