

510 (K) SUMMARY

DEC - 1 1997

- 1 Date of Summary Preparation**
Sept. 2, 1997
- 2 Submitter's Name & Address**
Innovasive Devices, Inc.
734 Forest Street,
Marlborough, MA 01752
Telephone: 508-460-8229
Fax: 508-460-8997
- 3 Contact Person**
MR. Eric Bannon
Vice President, QA/RA
- 4 Manufacturer's Contact Person**
Mr. T. Wade Fallin
Exec. Vice President
Innovasive Devices, Inc.
180 South 600 West
Logan, UT 84321
Telephone: 801-753-7675
Fax: 801-753-7698
- 5 Proprietary Device Name**
ACL Clip-In
- 6 Common Name**
Endosteal Fixation Device
- 7 Classification Name**
Smooth or Threaded Metallic Bone Fixation Fastener. Single/multiple component bone fixation appliances and accessories
- 8 Classification Reference**
21CFR 888.3030
- 9 Device Product Code**
87 MBI
- 10 Regulatory Class**
Class II

11 Materials

The following material is used in the manufacturing of the Base and Eyelets.
Ti-6Al-4V ELI per ASTM F-136.
Nitinol Wire (Ni-Ti Alloy)

12 Indications for Use

Innovasive Devices, Inc., ACL Clip-In is indicated for use in the fixation of ligament and tendon grafts in cruciate ligament reconstruction surgeries.

13 Description

Intended Use

The Innovasive Devices, Inc., ACL Clip-In is intended to be a fixation device in the repair of tendons and ligaments in Cruciate Reconstructive surgery.

Technological Characteristics

The ACL Clip-In device is a two component implant used in the fixation of ligament and tendon grafts in cruciate ligament reconstruction surgeries. The two device components are the Base and the Eyelet which are assembled together in the bone during the surgical procedure.

The ACL Clip-In device consists of an outer threaded Base which is designed to be endoscopically delivered through a prepared tibio-femoral tunnel and manually inserted into the antero-lateral femur using a hex driver. The proximal end of the Base has a flexible wire assembled to it.

The Eyelet has a smooth transverse opening to accept the soft tissue without damaging it. The proximal end of the Eyelet has a circular groove which is of a larger diameter of the flexible wire in the Base. The flexible wire provides for a spring like property as the Eyelet passes through the Base. When the proximal end of the Eyelet engages with the flexible wire, it locks the Eyelet in place.

With regard to implant size, the Base comes in 8mm, 10mm and 12mm diameters. The Eyelets are size specific and can be used only with the specified base component. The components will be labeled to indicate the same.

14 Substantially Equivalent Predicate Devices

TABLE
Predicate Devices Identification

MANUFACTURER'S NAME	DEVICE NAME	510(K) DOCUMENT NO.	510(K) CLEARED
Innovasive Devices, Marlborough, MA	8mm Ligament fastener	K970316	Yes

15 Substantial Equivalence

15.1 Technological Characteristics

15.1.1 Similarities

- (a) The ACL Clip-In device shares very similar technological characteristics with the predicate device. Both devices have:
 - 1) a bone fixation element, and
 - 2) a linkage element that connects the graft to the bone fixation element.
- (b) The bone fixation element is an externally threaded, internally cannulated Base.
- (c) The linkage element is an Eyelet with a transverse opening for receiving the graft and a proximal pin which locks into the Base.

15.1.2 Technological Differences

The ACL Clip-in uses different materials than the predicate device.

15.2 Rationale for Differences

- (a) The subject device uses a well proven material which provides for greater strength and biocompatibility.
- (b) Another potential clinical advantage is afforded by the connection means between the bone fixation element and the linkage element. This connection provides an axial lock, but will allow for rotational movement. Thus, the surgeon can adjust graft position along the axis of the bone tunnel after the linkage element, with graft attached, is connected to the bone fixation element. This is accomplished by engaging the Clip-In removal tool on the distal end of the Eyelet and turning it to reposition the graft in a distal to inferior direction.
- (c) A further potential clinical advantage is the ability to disengage the linkage element from the bone fixation element without damaging the linkage element or the graft by use of a simple removal punch. This may be an advantage in the event that the surgeon may need to reconfigure the linkage-graft construction. This removal tool engages the proximal end of the assembled bone fixation element and linkage element, and provides release with a rotationally directed compression force. Also provided is an implant removal tool, which helps unthread the assembly (base + eyelet) via the tibio-femoral tunnel.

16 Performance Data

No performance standards exist at this time for the regulatory class under which the ACL Clip-in is proposed for classification. However, in support of this submission, Innovative

Devices, Inc. has conducted the voluntary device testing in order to assess the effects of the new technological characteristics on the modes of failure of the device.

The effects of different materials on the modes of failure of the subject device were assessed in comparative testing with a selected predicate device.

The testing performed was:

- Strength of implant-implant interface
- Strength of implant-graft-host bone construct
 - a. Static
 - b. Dynamic

Post-test evaluation included:

- Host Bone- Implant Interface
- Graft - Implant Interface
- Graft Incorporation

With regard to testing, the subject device demonstrated at a minimum equivalent or better performance compared to the selected predicate device in each of the three tests outlined above. With regard to post test evaluation, the subject device demonstrate equivalent or better performance compared to the selected predicate device in post dynamic test evaluations of the host bone-implant interface and the graft-implant interface. Provisions for graft incorporation are essentially identical between the subject and predicate devices, as all provide transverse support of the soft tissue loop and all provide the same amount of graft-host bone surface area contact to facilitate graft incorporation.

17 Conclusion

Based on the design concept, use of standard material, feature comparisons to a selected predicate device, the device and predicate device testing, Innovasive Devices, Inc. believes that sufficient evidence exists to conclude that the ACL Clip-In Device is substantially equivalent to existing legally marketed endosteal fixation devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 1 1997

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

Re: K973323
Trade Name: ACL Clip-In
Regulatory Class: II
Product Code: MBI and HWC
Dated: September 2, 1997
Received: September 4, 1997

Dear Mr. Bannon:

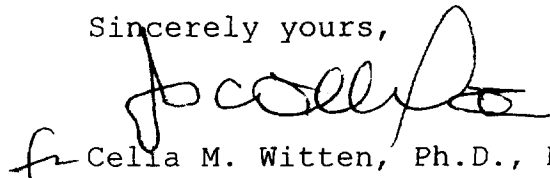
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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,


f 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

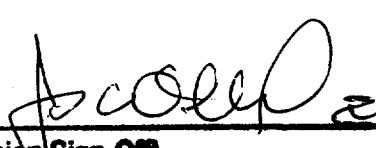
K973323

3. INDICATIONS FOR USE

3.1 Statement of Indications for Use

Innovative Devices, Inc. (IDI) - ACL Clip-In is indicated for use in the fixation of ligament and tendon grafts in cruciate ligament reconstruction surgeries.

Prescription Use _____
(Per 21 CFR 801.109)



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

K973323