



K993975

DEC 20 1999

**510(K) SUMMARY**  
**Special 510(k)**

**1. SUBMITTER:**

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

Contact: Kathleen Morahan, Regulatory Affairs Specialist  
Date Prepared: November 19, 1999

**2. DEVICE:**

Trade Name: Innovative Absolute™ Absorbable Interference Screw (11mm and 12mm)

Common Name: Interference Screw

Classification Name: Not Classified

**3. PREDICATE DEVICE:**

(1) Innovative Bio-Interference Screw - K900454

**4. DEVICE DESCRIPTION:**

The Absolute™ Absorbable 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 11mm and 12mm diameters and 30mm in length.

**5. INTENDED USE:**

The Absolute™ Absorbable 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 Absolute™ Absorbable Interference Screw is identical to the Bio-absorbable Interference Screw with the exception of the outside diameter. Both devices are cannulated, threaded, tapered, and molded from the same material: Poly-L-Lactide (L-PLA).

The indication being requested for the Absolute™ Absorbable Interference Screw is already cleared for predicate Bio-Interference Screw.

## **7. PERFORMANCE DATA:**

The following performance testing was performed in support of the substantial equivalence determination:

Bone Model Testing: the ultimate holding strength of the Absolute™ Absorbable Interference Screw, the force to insert and strip the screw.

The testing demonstrates substantially equivalent performance between the proposed and predicate devices.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Kathleen Morahan  
Regulatory Affairs Specialist  
Innovasive Device, Inc.  
734 Forest St.  
Marlborough, MA 01752

Re: K993975  
Trade Name: Absolute Absorbable Interference Screw  
Regulatory Class: II  
Product Code: HWC  
Dated: November 19, 1999  
Received: November 24, 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 (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 at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



James E. Dillard III  
Acting Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K993975

**INDICATIONS FOR USE**

11mm & 12mm Absolute™ Absorbable Interference Screw

The 11mm & 12mm Absolute™ Absorbable Interference Screws are intended for fixation of soft tissue grafts or bone-tendon-bone grafts during cruciate ligament reconstruction surgeries of the knee.

Division Sign-Off) MRD for  
Division of General Restorative Devices K993975  
510(k) Number \_\_\_\_\_

Prescription Use YES  
(Per 21 CFR 801.109)