K992377

INNOVASIVE DEVICES

OCT 8 1999

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: July 9, 1999

2. DEVICE:

Trade Name: RC Tack

Common Name: Bone Anchor

Classification Name: "Single/Multiple Component Bone Fixation Appliances and Accessories"

3. PREDICATE DEVICE:

The Innovasive ROC EZ Suture Bone Fastener (K970089, K971922).

4. DEVICE DESCRIPTION:

The RC Tack is a polymmer implant intended for soft tissue reattachment to host bone in the shoulder, knee, and ankle. The implant consists of three components: a tip, sleeve, and pin. Upon deployment, the pin is driven into the sleeve expanding the sleeve radially to gain bone fixation. The RC Tack is a sterile single use device offered in one size, 4.5mm.

5. INTENDED USE:

The proposed RC Tack is intended for soft tissue reattachment to host bone for the following indications:

SHOULDER

Repair of rotator cuff tears
Acromio-clavicular separation
Biceps tenodesis
Deltoid repair

KNEE

Extra-Capsular repairs
Reattachment of medial collateral ligament
Reattachment of lateral collateral ligament
Reattachment of posterior oblique ligament
Joint capsule closure
Patellar ligament and tendon avulsion repairs
Extra-capsular reconstruction
ITB tenodesis

ANKLE

Lateral and medial instability
Achilles tendon reconstruction and repair

6. COMPARISON OF CHARACTERISTICS:

The proposed RC Tack and the predicate ROC EZ Suture Bone Fastener implants utilize the same materials. Both devices also utilize the same method of bone fixation: radially expansion of the sleeve. Lastly, the indications being requested for the proposed RC Tack are already cleared for the ROC EZ Suture Bone Fastener.

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 RC Tack was compared to Innovasive's currently marketed ROC EZ Suture Bone Fastener and the ConTack Fastener. The ConTack Fastener was chosen as a second comparison device because it tack soft tissue to bone, although its materials and design differ from the proposed RC Tack. The proposed RC Tack holding strength was greater than that of the predicate device and the ConTack Fastener, demonstrating substantially equivalent performance between the devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 8 1999

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

Re: K992377
Trade Name: RC Tack Bone Anchor
Product Code: MBI
Regulatory Class: II
Dated: July 9, 1999
Received: July 15, 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

K992377

INDICATIONS FOR USE

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Extra-capsular reconstruction
ITB tenodesis

ANKLE

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Achilles tendon reconstruction and repair

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992377