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510(K) SUMMARY

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: December 17, 1999

2. DEVICE:

Trade Name: Innovative Titan RC Tack
Common Name: Bone Anchor
Class: II
Classification Name: "Single/Multiple Component Bone Fixation Appliances and Accessories"

3. PREDICATE DEVICE:

Innovative RC Tack (K992377)

4. DEVICE DESCRIPTION:

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

5. INTENDED USE:

The Titan RC Tack is intended for fixation of soft tissue to 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 Titan RC Tack, is a bioabsorbable version of the predicate RC Tack, and is therefore similar in design. The proposed device is molded from L-PLA with a color additive for implant visibility. The predicate device is molded from Delrin and HDPE. The proposed and predicate devices utilize the same method of bone fixation: radial expansion of the sleeve. Lastly, the indications being requested for the proposed Titan RC Tack are already cleared for the predicate RC Tack.

7. PERFORMANCE DATA:

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

Bone Model Testing: the ultimate holding strength at 3, 6, and 12 weeks in-vitro.

The testing demonstrates substantially equivalent performance between the two devices



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K994269
Titan RC Tack
Product Code: MAI
Regulatory Class: II
Dated: December 17, 1999
Received: December 20, 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.

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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,



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

Enclosure

INDICATIONS FOR USE

The Titan RC Tack is intended for soft tissue to bone fixation 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

Prescription Use X
(Per 21 CFR 801.109)

Kenneth Jayson 52571
 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K994269