

JUN 16 1998

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

Innovasive Devices, Inc.
734 Forest St.
Marlborough, MA 01752
Telephone: 508-460-8229
Contact: Stephen M. Page, Manager of Regulatory Affairs
Date Prepared: March 31, 1998

2. DEVICE:

Innovasive 3.5mm Metal ROC XS Suture Bone Fastener
Classification Name: Single/multiple component bone fixation appliances and accessories.
Trade Name: Innovasive Devices 3.5mm Metal ROC XS Suture Bone Fastener

3. PREDICATE DEVICES:

The predicate devices used to determine substantial equivalence for the modified Innovasive Devices 3.5mm Metal ROC XS Suture Bone Fastener were:

- a. The 3.5mm Innovasive Devices ROC XS Suture Bone Fastener, marketed by Innovasive Devices, Marlborough, MA, and
- b. The 3.5mm Innovasive Devices ROC EZ Suture Bone Fastener marketed by Innovasive Devices, Marlborough, MA.

4. DEVICE DESCRIPTION:

The 3.5mm Metal ROC XS suture bone fastener implant tip portion consists of a shear pin, crown and anvil. The crown and anvil are fitted onto the shear pin component such that the crown component is located below the anvil on the shear pin. As the crown is pulled up during the device deployment, the anvil forces it open. The anvil is tapered such that it will fit into the crown component as the deployment action progresses. As the crown is forced open by the anvil, the crown expands to make contact with the surrounding bone. This expanding crown results in the final fixation properties of the device. Once the anvil is completely seated inside the crown, the shearing pin shears from the fastener assembly resulting in the device being fixated into the bone hole.

In addition to the Fastener, a stainless steel drill and drill guide is available to establish the proper hole in the bone for the Fastener along with a deployment handle and hole finder. All of the instrumentation except the Fastener will be offered as reusable devices and can be autoclaved in the sterilization tray provided for this purpose.

The 3.5mm Metal ROC XS will be available as a sterile, single use device. Both sutured and sutureless versions will be marketed.

5. INTENDED USE:

The 3.5mm Metal ROC XS Suture Bone Fasteners are intended for the reattachment of soft tissue to bone for the following indications:

SHOULDER

Bankart repair
 Repair of rotator cuff tears
 Capsular instability
 Slap lesion repair
 Acromio-clavicular separation
 Capsule shift/capsulolabral reconstruction
 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 repair
 Extra-capsular reconstruction
 ITB tenodesis

ANKLE

Lateral and medial instability
 Achilles tendon reconstruction and repair
 Mid-foot reconstructions

ELBOW

Tennis elbow repair
 Biceps tendon reattachment
 Medial and lateral repairs

FOOT

Hallux valgus reconstruction

BLADDER NECK SUSPENSION

Bladder neck suspension for female urinary incontinence due to urethral hypermobility

6. COMPARISON OF CHARACTERISTICS:

The existing Innovative Devices 3.5mm ROC XS and 3.5mm ROC EZ Suture Bone Fasteners are comprised of plastic. The devices are used to secure a suture in a predrilled hole in bone. They remain fixed in the bone through radial compression as the device is deployed.

The proposed 3.5mm Metal ROC XS, as the name suggests, is made of stainless steel. The proposed Indications for Use are identical to those of the existing 3.5mm ROC EZ. As with the existing devices, the proposed 3.5mm Metal ROC XS will be offered with #2 Suture, both with and without stainless steel needles.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Stephen M. Page
Manager of Regulatory Affairs
Innovative Devices, Inc.
734 Forest Street
Marlborough, Massachusetts 01752

Re: K981193
Innovative 3.5 mm Metal ROC XS Suture Bone Fastener
Regulatory Class: II
Product Codes: MBI and HWC
Dated: March 31, 1998
Received: April 2, 1998

Dear Mr. Page:

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.

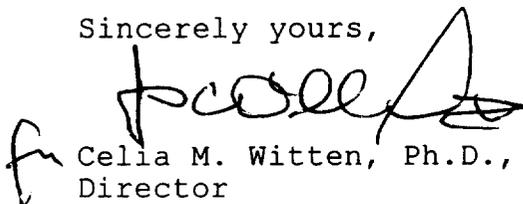
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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,



f 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

SHOULDER

- Bankart repair
- Repair of rotator cuff tears
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- 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
- Mid-foot reconstructions

FOOT

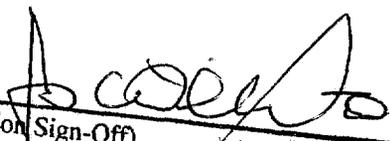
- Hallux valgus reconstruction

ELBOW

- Tennis elbow repair
- Biceps tendon reattachment
- Medial and lateral repairs

BLADDER NECK SUSPENSION

Bladder neck suspension for female urinary incontinence due to urethral hypermobility.


 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K981193

Prescription Use X
 (Per 21 CFR 801.109)