

510(K) SUMMARY

AUG - 7 1997

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: May 21, 1997

2. DEVICE:

Innovasive 2.8mm and 3.5mm ROC EZ Suture Bone Fastener
Classification Name: Single/multiple component bone fixation appliances and accessories.
Trade Name: Innovasive Devices ROC EZ Suture Bone Fastener

3. PREDICATE DEVICE:

The predicate device used to determine substantial equivalence for the modified Innovasive Devices ROC EZ Suture Bone Fastener was the 2.8mm and 3.5mm Innovasive Devices ROC EZ Suture Bone Fastener, marketed by Innovasive Devices, Marlborough, MA.

4. DEVICE DESCRIPTION:

The ROC EZ suture bone fastener implant tip portion consists of a shear pin, expander and sleeve. The expander and sleeve is fitted onto the shear pin component such that the expander component is located below the sleeve on the shear pin. As the shear pin is pulled up during the device deployment, the expander engages the sleeve. The expander is tapered such that it will fit into the sleeve component as the deployment action progresses. As the expander is drawn into the sleeve, the sleeve expands to make contact with the surrounding bone. This expanding sleeve results in the final fixation properties of the device. Once the expander is completely seated inside the sleeve, 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 an obturator, 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 Fastener will be available as a sterile, single use device in both an open and arthroscopic version. Both sutured and sutureless versions will be marketed.

5. INTENDED USE:

The 2.8mm and 3.5mm ROC EZ Suture Bone Fasteners are intended for the reattachment of soft tissue to bone for the following indications:

000494

SHOULDER

1. Repair of rotator cuff tears
2. capsular instability
3. slap lesion repair
4. acromio-clavicular separation
5. capsule shift/capsulolabral reconstruction
6. biceps tenodesis
7. deltoid repair

KNEE

1. Extra-capsular repairs, and reattachment of medial collateral ligament, lateral collateral ligament, posterior oblique ligament, joint capsule closure.
2. Patellar ligament and tendon avulsion repairs.
3. Extra-capsular reconstruction, ITB tenodesis

ANKLE

1. Lateral instability
2. Medial instability
3. Achilles tendon reconstruction and repair
4. Mid-foot reconstructions

FOOT

1. Hallux valgus reconstruction

ELBOW

1. Tennis elbow repair
2. Biceps tendon reattachment
3. Medial and lateral repairs

BLADDER NECK SUSPENSION

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

6. COMPARISON OF CHARACTERISTICS:

The existing Innovasive Devices ROC EZ Suture Bone Fastener is comprised of two polymer components, high density polyethylene and acetyl plastic. This device is used to secure a suture in a predrilled hole in bone. It remains fixed in the bone through radial compression as the device is deployed. This remains true for all sizes of the device.

The modified ROC EZ device is comprised of high density polyethylene and polysulfone. As with the predicate device, the modified ROC EZ uses an expander fitted on a shear pin which is drawn up into an expandable sleeve. The sleeve expands as the expander is drawn up into it. The shear pin then shears resulting in the device being fixed into the bone site.

7. PERFORMANCE DATA:

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

1. Bone model testing: Comparison of the ultimate holding strength in a bone model compared to the predicate device. The Innovasive ROC EZ Suture Bone Fastener holding strength was found to be equivalent to the strength of the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K971922
Innovasive 2.8mm and 3.5mm ROC™
EZ Suture Bone Fastener
Regulatory Class: II
Product Codes: MBI and HRX
Dated: May 21, 1997
Received: May 23, 1997

AUG - 7 1997

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.

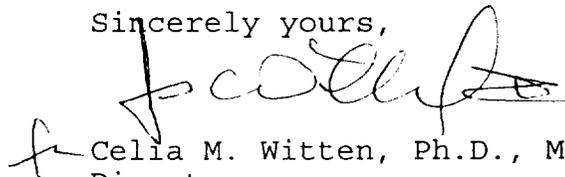
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Mr. Stephen M. Page

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,



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
- 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 repairs
- extra-capsular reconstruction
- ITB tenodesis.

ANKLE

- Lateral and medial instability
- achilles tendon reconstruction and repair
- mid-foot reconstructions.

FOOT

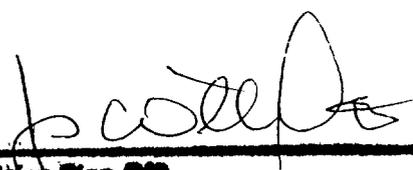
- Hallux valgus reconstruction

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.



Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971922

0094