SEP 2 6 1997 **510(K) SUMMARY**

K972438

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: June 27, 1997

2. DEVICE:

Innovasive 2.3mm ROC XS Suture Bone Fastener
Classification Name: Single/multiple component bone fixation appliances and accessories.
Trade Name: Innovasive Devices ROC XS Suture Bone Fastener

3. PREDICATE DEVICES:

The predicate devices used to determine substantial equivalence for the modified Innovasive Devices 2.3mm ROC XS Suture Bone Fastener were:

a. The 3.5mm Innovasive Devices ROC XS Suture Bone Fastener, marketed by Innovasive Devices, Marlborough, MA,
b. The 1.9mm/2.3mm Innovasive Devices ROC Suture Bone Fastener marketed by Innovasive Devices, Marlborough, MA, and
c. The 1.8mm Mitek Mini Anchor marketed by Mitek Products, 60 Glacier Drive, Westwood, MA.

4. DEVICE DESCRIPTION:

The 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.

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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 Fastener will be available as a sterile, single use device. Both sutured and sutureless versions will be marketed.

5. INTENDED USE:

The 2.3mm ROC XS Suture Bone Fasteners are intended for the reattachment of soft tissue to bone for the following indications:

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

HAND
1. Ulnar or lateral collateral ligament reconstruction

WRIST
1. Scapholunate ligament reconstruction

FOOT
1. Hallux valgus reconstruction

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

6. COMPARISON OF CHARACTERISTICS:

The existing Innovasive Devices 3.5mm ROC XS Suture Bone Fastener components are comprised of 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 2.3mm ROC XS device incorporates the same design as the existing 3.5mm ROC XS. The only differences are the size (2.3mm) and the material composition of the anvil (polysulfone). As with the predicate device, the 2.3mm ROC XS uses a crown and anvil fitted on a shear pin such that the crown component is located below the anvil on the shear pin. As the crown is pulled up during device deployment, the anvil forces it open. 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 devices. The Innovasive 2.3mm ROC XS Suture Bone Fastener holding strength was found to be equivalent to the strength of the predicate devices.
2. Cadaver testing: Comparison of the ultimate holding strength in cadaver compared to the predicate device. Again, the Innovasive 2.3mm ROC XS Suture Bone Fastener holding strength was found to be equivalent to the strength of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

SEP 26 1997

Re: K972438
Innovasive 2.3mm ROC™ XS Suture Bone Anchor
Regulatory Class: II
Product Code: MBI
Dated: June 27, 1997
Received: June 30, 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 (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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for 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

ANKLE
Lateral instability
Medial instability
Achilles tendon reconstruction and repair
Midfoot reconstructions

HAND
Ulnar or lateral collateral ligament reconstruction

WRIST
Scapholunate ligament reconstruction

FOOT
Hallux valgus reconstruction

ELBOW
Tennis elbow repair
Biceps tendon reattachment
Medial and lateral repairs

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972438

Prescription Use X
(Per 21 CFR 801.109)

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