3/1/99

INNOVASIVE DEVICES

K984490

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: December 16, 1998

2. DEVICE:

Trade Name: Sutureless Anchor

Common Name: Bone Anchor

Classification Name: Not Classified

3. PREDICATE DEVICE:

(1) the Acufex SureTac - K911837
(2) the Innovasive BioROC EZ Fastener - K973381

4. DEVICE DESCRIPTION:

The Sutureless Anchor is a biodegradable bone anchor intended for soft tissue to bone fixation in the repair of shoulder injuries. The device is offered in one size, 7.0mm. The Sutureless Anchor implant consists of three components: a sleeve, pin and washer. Upon deployment, the pin is driven through the center of the washer into the sleeve, expanding the sleeve radially to gain bone fixation. Simultaneously, a shearing mechanism releases the implant from the deployment shaft. The washer, fastened to the implant by the pin head, remains above the bone surface, tacking the soft tissue to the bone.

5. INTENDED USE:

The proposed Sutureless Anchor is intended for soft tissue to bone fixation for reattachment of the glenoid labrum and/or inferior glenohumeral ligament in patients with primary or recurrent anterior dislocation or subluxation of the shoulder.

6. COMPARISON OF CHARACTERISTICS:

The bone fixation mechanism of the proposed Sutureless Anchor is same as the predicate BioROC EZ: a pin is driven into the sleeve expanding the sleeve radially to gain bone fixation. The BioROC EZ is also cleared for the same indications and utilizes the same biodegradable material as two of the proposed Sutureless Anchor implant components.

The predicate SureTac device and the proposed Sutureless Anchor have the same intended use, and are similar in that both devices anchor soft tissue to bone without the use of suture. However, the SureTac is a one piece device that is driven into the bone, while the proposed Sutureless Anchor consists of three components and is deployed into the bone fixated by expansion of the sleeve. The material of these devices also differs.

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 Sutureless Anchor was compared to the currently marketed SureTac. The proposed Sutureless Anchor holding strength mean at time zero, and at six weeks in-vitro, was greater than that of the predicate device, demonstrating substantially equivalent performance between the two devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 1999

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

Re: K984490
Trade Name: Sutureless Anchor
Regulatory Class: II
Product Code: MAI
Dated: December 16, 1998
Received: December 17, 1998

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 (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

510(k) Number (if known): K984490

Device Name: Sutureless Anchor

Indications For Use:

The Sutureless Anchor is intended for soft tissue to bone fixation for reattachment of the glenoid labrum and/or inferior glenohumeral ligament in patients with primary or recurrent anterior dislocation or subluxation of the shoulder.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Y/N
(Per 21 CFR 801.109)

OR

Over-The-Counter Use No

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984490