OCT 0 4 2002

K022207
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SUMMARY OF SAFETY AND EFFECTIVENESS

General Company Information

Name: Axya Medical, Inc.

Address: 100 Cummings Center
Suite 444C
Beverly, MA 01915

Telephone: (978) 232 - 9997
Fax: (978) 232 - 9998

General Device Information

Product Name: Model 3000 AxyaLoop™ Titanium Bone Anchor

Classification: "Non-degradable soft tissue fixation fastener", Product code: MBI
Class II

Predicate Devices

Axya Medical, Inc. Model 1000 AxyaLoop™ Suture Anchor
[501(k) Number K003971]

Orthopaedic Biosystems Mini Tac 2.0 mm Bone Anchor
[510(k) Number K000797]

Description

The device described in this submission is designed with a corkscrew style thread and is available in a 2.0 mm diameter specifically for use in ankle, foot, elbow, wrist and hand repairs and reconstructions. The Axya Bone Anchor is available as a system together with a drill bit, a delivery/extraction handle and a drill guide. These accessories are the same types of instruments included in procedure sets for currently marketed bone anchor systems. Axya Medical believes that the accessory instruments are Class I Manual Surgical Instruments and are exempt from the premarket Notification regulations. The Axya Model 3000 Titanium Bone Anchor is prethreaded with size 2/0 USP non-absorbable monofilament suture material. The suture is a legally marketed material, manufactured by one of several contract suppliers. The Model 3000 Titanium Bone Anchor is intended for use in both standard open surgical procedures and in minimally invasive (arthroscopic) surgical procedures.

Indications

The Axya Model 3000 AxyaLoop™ Titanium Bone Anchor System is indicated for securing soft tissue to bone with size 2/0 synthetic non-absorbable suture in repairs of the extremities such as those shown below:

Foot and Ankle
1 Hallux Valgus repairs
2 Medial or lateral instability repairs/reconstructions
3 Achilles tendon repairs/reconstructions
4 Midfoot reconstructions
5 Metatarsal ligament/tendon repairs/reconstructions

Elbow wrist and Hand
1 Scapholunate ligament reconstructions
2 Ulnar and radial collateral ligament reconstructions
3 Lateral epicondylitis repair
4 Biceps tendon reattachment

Substantial Equivalence

This submission supports the position that the Axya Model 3000 Titanium Bone Anchor is substantially equivalent to a number of previously cleared devices, including those referenced above.

The 510(k) Notice contains summaries of an *in vitro* study that was conducted to evaluate the anchor pull-out strength as specified in the FDA Guidance Document for Testing Bone Anchor Devices (dated April 20, 1996). The data presented demonstrate that the anchor pull-out force of the Axya Model 3000 AxyaLoop Titanium Bone Anchor compared favorably with the predicate device of similar diameter and corkscrew geometry (OBL 2.0 mm Mini Tac). The failure mode observed for the Axya anchor and the predicate anchor was the same (i.e. anchor pull-out).

The single-patient-use components of the bone anchor system are provided sterile. The suture material and bone anchors are sterilized by a process equivalent to the process used by the original suture manufacturer.

Axya Medical, Inc. believes that the information provided establishes that similar legally marketed bone anchors have been used for the same clinical applications as the Axya Model 3000 Titanium Bone Anchor. The materials from which the Axya device is fabricated have an established history of use in medical applications, and the devices produced by Axya have been tested in accordance with applicable FDA guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 4 2002

Mr. Howard L. Schrayer
Axya Medical, Inc.
100 Cummings Center, Suite 444C
Beverly, Massachusetts 01915

Re: K022207
Trade/Device Name: Model 3000 AxyaLoop™ Titanium Bone Anchor System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Codes: MBI, HWC, GAS
Dated: July 3, 2002
Received: July 8, 2002

Dear Mr. Schrayer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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.

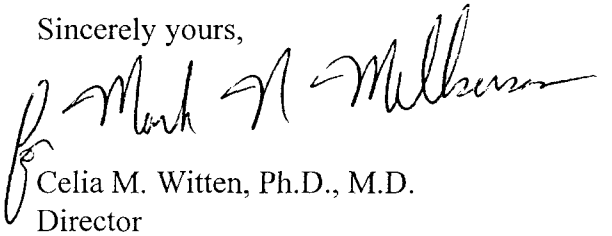
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022207

Device Name: Axya, Model 3000 AxyaLoop™ Titanium Bone Anchor

Indications For Use:

The Axya Model 3000 AxyaLoop™ Titanium Bone Anchor System is indicated for securing soft tissue to bone with size 2/0 synthetic non-absorbable suture in repairs of the extremities such as those shown below:

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1 Hallux Valgus repairs
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Elbow, Wrist and Hand
1 Scapholunate ligament reconstructions
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3 Lateral epicondylitis repair
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022207

Prescription Use_____ **OR** **Over-The-Counter Use**_____
(Per 21 CFR 801.109)