K070773 page 1 of 2

OCT 11 2007

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Per 21 CFR 807.92)

General Company Information

Name: Axya Medical, Inc.
Contact: Howard Schrayer
Regulatory Affairs Consultant

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

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

Date Prepared March 20, 2007

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 3000 AxyaLoop™ Suture Anchor
[501(k) Number K022207]

Depuy Mitek QUICKANCHOR Plus Bone Anchor
[510(k) Number K041115]

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. The Axya Model 3000 Titanium Bone Anchor is prethreaded with either non-absorbable suture or size 3/0 TephaFLEX™ suture material.

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 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 manufacturers.

Conclusions

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

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

OCT 11 2007

Re: K070773
Trade/Device Name: Model 3000 AxyaLoop™ Titanium Bone Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI, JDR, HWC, MAI
Dated: September 14, 2007
Received: September 17, 2007

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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K070773

Device Name: Axya, Model 300 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 or size 3/0 TephaFLEX™ 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

Prescription Use X **AND/OR** **Over-The-Counter Use** No
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buch MD

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

510(k) Number K070773