K041698 page 1 of 3

OCT 5 - 2004

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
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Date Prepared June 19, 2004

General Device Information

Product Name: Model 5000 AxyaLoop™ Bio-Absorbable Bone Anchor

Classification: "Biodegradable soft tissue fixation fastener"
Product code: MAI Class II

Predicate Devices

Arthrex Inc. Bio-Absorbable Corkscrew Suture Anchor
Model AR-1920B [501(k) Number K003227]

Mitek Worldwide Biofastin RC Threaded Suture Anchor
[510(k) Number K021883]

Description

The device described in this submission is designed with a corkscrew style thread and will be made available initially in a 5.0 mm nominal diameters, for use in a range of soft tissue to bone attachment procedures. The Axya Bone Anchor will be made available as a system together with a thread tap and a placement tool (driver). 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 5000 Bio-Absorbable Bone Anchor is prethreaded with USP polypropylene monofilament, USP nylon, USP braided polyester and USP braided polyethylene suture materials.

The Model 5000 Bio-Absorbable Bone Anchor is designed for use in both standard open surgical procedures and in minimally invasive (arthroscopic) surgical procedures.

Intended Use (Indications)

The Axya Model 5000 AxyaLoop™ Bio-Absorbable Bone Anchor is indicated for securing suture to bone. This device is intended for use in the following applications:

Shoulder: Rotator cuff, Bankart, and SLAP lesion repair, Biceps tenodesis, Acromio-Clavicular separation and Deltoid repair, Capsular shift and Capsulolabral reconstruction

Foot/Ankle: Lateral and Medial stabilization, Achilles tendon and Metatarsal ligament repair, Hallux Valgus and Midfoot reconstruction

Knee: Medial collateral and Lateral collateral ligament repair, Patellar tendon and Posterior oblique ligament repair, Iliotibial band tenodesis

Hand/Wrist: Scapholunate ligament, Radial collateral ligament and Ulnar collateral ligament reconstruction

Elbow: Biceps tendon reattachment, Tennis elbow repair, Ulnar and Radial collateral ligament reconstruction

Pelvis: Bladder neck suspension for urinary incontinence due to urethral hypermobility or intrinsic sphincter deficiency in females

Substantial Equivalence

This submission supports the position that the Axya Model 5000 Bio-Absorbable Bone Anchor is substantially equivalent to a number of previously cleared devices, including the the Arthrex Inc. Bio-absorbable Corkscrew Model AR-1920B Suture Anchor [501(k) Number K003227] and the Mitek Worldwide Biofastin RC Threaded Suture Anchor [510(k) K021883].

The 510(k) Notice contains summaries of *in vitro* studies that were 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 5000 AxyaLoop Bio-Absorbable Bone Anchor compared favorably with the predicate device of similar corkscrew geometry. The failure mode observed for the Axya anchor was predominately the same as that of the predicate anchor.

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.

Conclusions

Axya Medical, Inc. believes that the information provided establishes that similar legally marketed have been used for the same clinical applications as the Axya Model 5000 Bio-Absorbable Bone Anchor. The materials from which the Axya device is fabricated have an established history of use in medical applications, and 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 5 - 2004

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

Re: K041698
Trade/Device Name: Axya, Model 5000 AxyaLoop™ Bio-Absorbable Bone Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: MAI
Dated: June 19, 2004
Received: July 7, 2004

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 (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. 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,

for Celia M. Witten, PhD, MD
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): K041698

Device Name: Axya, Model 5000 AxyaLoop™ Bio-Absorbable Bone Anchor

Indications For Use:

The Axya Model 5000 AxyaLoop™ Bio-Absorbable Bone Anchor is indicated for securing suture to bone. This device is intended for use in the following applications:

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Pelvis: Bladder neck suspension for urinary incontinence due to urethral hypermobility or intrinsic sphincter deficiency in females

Prescription Use Yes **AND/OR** **Over-The-Counter Use** No
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(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 K041698