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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: Bone Anchor System and Kit (BAK)

Classification: Accessory to an Endoscope – Class II

Predicate Devices

Axya Suturing and Ligating System (ASLS) [510(k) K980988]

Axya Suture Welding System and Kit (SWK) [510(k) K983108]

Description

The Axya Bone Anchor System consists of an electronic control module and a reusable welding activator with an integral connector cable. The Kit (BAK) consists of a disposable suture welding sleeve packaged together with appropriate and currently approved bone anchors and USP polypropylene monofilament suture. The Kit is intended for use with the reusable system components in order to complete the suture welding process for the attachment of soft tissues to bone anchors in surgical procedures where bone anchors are indicated

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Intended Use

The Bone Anchor System and Kit is indicated for securing soft tissue structures to bone anchors in surgical procedures where bone anchors are indicated. Examples of these procedures include:

Shoulder procedures	(e.g. Rotator cuff repair)
Knee procedures	(e.g. Patellar ligament / tendon avulsion repair)
Ankle procedures	(e.g. Achilles tendon reconstruction and repair)
Foot procedures	(e.g. Hallux valgus reconstruction)
Elbow procedures	(e.g. Biceps tendon reattachment)
Bladder neck suspension	(female urinary incontinence due to urethral hypermobility)

The BAK is indicated for use in both traditional open surgery and endoscopic surgical procedures.

Substantial Equivalence

This submission supports the position that the Axya Bone Anchor System and Kit (BAK) is substantially equivalent in design and function to the Axya Suturing and Ligating System (ASLS) [510(k) K980988], the Axya Suture Welding System and Kit (SWK) [510(k) K983108] and the Endo-Judge disposable suture placement system developed by Synergistic Medical Technologies and marketed by Ethicon Endosurgery [510(k) K932591], and that it is appropriate for its intended application. Suture applicators and suture placement devices which may be used in both endoscopic or traditional open surgical procedures have been classified under 21 CFR 876.1500. These devices are indicated for the placement of sutures to close either traumatic or surgically produced wounds. The BAK is fabricated from materials with a substantial history of use in medical devices. Both the BAK and the predicate devices secure the suture loop with an ultrasonic weld.

The 510(k) Notice for the predicate ASLS system contains summaries of both *in vivo* and *in vitro* studies which were conducted to evaluate the safety, efficacy and appropriateness of the suture welding system. These data are applicable to the Bone Anchor System because the design and components of the welding mechanism are the same as those used in both the ASLS and the SWK that were previously cleared for marketing. Data were presented which demonstrate that sutures placed by means of the suture welding process exhibit "knot strength" characteristics substantially above the USP requirements for the respective sizes and types of suture materials tested. These tests confirm that the polypropylene monofilament sutures placed with the ultrasonic suture welding technology are equivalent in holding strength (efficacy) to sutures placed with conventional knotting techniques.

Additional data presented in the Notice for the Bone Anchor System and Kit confirm that USP size 2 polypropylene monofilament sutures secured by a weld formed with the AxyaWeld Tips exceed the USP knot strength requirements. Data have been presented that demonstrate that strength requirements are met regardless of the angle of applied tension between the suture

and the bone anchor stem. Suture fatigue and elongation over the functional life have been evaluated in bench-test models and the welded sutures have been found to meet the suggested criteria following cyclic testing.

The safety of the suture delivery system was previously evaluated by placing both welded sutures and manually knotted sutures in the dorsal skin and in bowel tissue of New Zealand rabbits [510(k) K980988]. Positive (electrocautery contact) and negative (normal tissue) controls were used in the bowel study. In both animal models there was no histopathologic change seen at the suture implant sites where the suture was sealed with ultrasonic energy. The investigators concluded that there was no significant difference in safety of efficacy between the traditional method of suture placement and the technique which includes replacement of manual knot-tying with suture welding. The design of the AxyaWeld Sleeve also prevents the heated area of suture from coming into direct contact with tissues.

The ultrasonic energy source used to weld and secure the suture loop is the same generator used for the Automatic Suturing and Ligating System and that used for the Suture Welding System and Kit, and is similar to the energy source used in the UltraCision Harmonic Scalpel [510(k) K895252].

Because of design features of the BAK, no portion of the ultrasonic generator comes into contact with human tissues. Because of this, there is virtually no risk of causing a thermal injury to the patient. The suture material is heated and welded by friction and the weld is formed by melting and fusing the polymer. No "flux" or "welding rod" is employed and no new chemical entities are introduced or produced in the welding process.

The Axya Bone Anchor System and Kit are sterilized by exposure to gamma irradiation at 2.5 Mrads which provides a sterility assurance level of at least 10^{-6} or, alternatively, by means of an ethylene oxide gas sterilization process which also provides a SAL of 10^{-6}. The sterility process selected is dictated by the type of suture included with a given product configuration. These sterility processes, the manufacturing process, and the packaging process are validated by the manufacturer.

Axya Medical, Inc. believes that the information provided establishes that similar legally marketed and pre-enactment devices have been used for the same types of clinical applications as the Axya Bone Anchor System and Kit. The materials from which the Axya device is fabricated have an established history of use in medical applications, and the specific materials used by Axya have been thoroughly 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

SEP 22 1999

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

Re: K992405
Trade Name: Axya Bone Anchor System and Kit
Regulatory Class: II
Product Code: GAW and MBI
Dated: July 19, 1999
Received: July 20, 1999

Dear Mr. Schrayer:

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 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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.

FDA notes that your device will contain sutures for which you have provided evidence that the suture characteristics are not altered by the sterilization process used in the device. However, you should be aware of the following additional information regarding the inclusion of a suture as a component of your device:

1. The labeling, packaging and method of sterilization of the suture cannot be changed without prior notification, review and clearance by FDA.

2. The supplier of the sutures used in your device cannot be changed without prior notification, review and clearance by FDA.

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 the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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/dsma/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): 510(k) K992405

Device Name: Axya, Bone Anchor System and Kit, (BAK)

Indications For Use:

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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)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992405