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

General Company Information:

JUL 11 2007

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Date Prepared: July 11, 2007

General Device Information:

Product Name: Axya™ Suture Welding System with
Axya Medical Tufflex™ Polyester Suture

Classification:

Nonabsorbable Poly[Ethylene Terephthalate] Suture
Class II - Product Code: GAT - 21 CFR § 878.5000
Ligature Passing and Knot Tying Instrument - Class I
Product Code: HCF

Predicate Devices:

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

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

Description:

The Suture Welding System described in this Notice is a fully disposable single-patient-use hand-piece with an internal (battery) power supply/controller. This device is designed for use in securing a specific suture (Axya Medical Tufflex™ Polyester suture) with a weld rather than with a traditional knot. This reduces the bulk of the suture fastening point and eliminates the possibility of knot slippage. The single-patient-use device eliminates the need for repair and maintenance of suture welding devices with reusable power supply/control units.

Intended Use (Indications):

The Axya Suture Weld System is indicated for use in securing sutures in soft tissues and for securing ligatures of tubular structures wherever conventional sutures or surgical staples are appropriate. The System may be used in arthroscopic, laparoscopic and open surgical procedures.

Substantial Equivalence:

This submission supports the position that the Axya Suture Welding System and Kit, which may include Tufflex™ polyester suture, is substantially equivalent to the Axya Suture Welding System and Kit (SWK) [510(k) K983108]; 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 device is fabricated from materials with a substantial history of use in medical devices. Both the modified device and the predicate devices secure the suture loop with a weld.

The 510(k) Notice for the system contains references to and summaries of both *in vivo* and *in vitro* studies which were conducted to evaluate the safety, efficacy and appropriateness of the suture welding system. Data were presented which demonstrate that sutures placed by means of the suture welding process exhibit "knot strength" characteristics above the USP requirements for the USP suture material tested. These tests confirm that sutures placed with the suture welding technology are equivalent in holding strength (efficacy) to sutures placed with conventional knotting techniques. Additional data were presented that demonstrated that sutures welded in a fluid environment meet USP knot strength requirements. This supports the use of the system in closed endoscopic (arthroscopic) procedures.

The safety of the Suture Welding System was evaluated by placing both welded sutures and manually knotted sutures in bowel tissue of the New Zealand rabbit. Positive (electrocautery) and negative (normal tissue) controls were used in the bowel study. In this animal model there was no unusual adverse histopathologic change seen at the suture implant sites where the suture was welded. The investigators concluded that there was no significant difference in safety of efficacy between the traditional method of suture placement and the technique which replaces manual knot-tying with suture welding. The design of the device protects tissues from potential thermal injury.

No "flux" or "welding rod" is employed and no new chemical entities are introduced or produced in the welding process.

The single-patient-use components of the System and Kit are provided sterile. The sterility processes, the manufacturing process, and the packaging process are validated by the manufacturer.

Conclusions

Axya Medical, Inc. believes that the information provided establishes that similar legally marketed devices have been used for the same clinical applications as the Axya Suture Welding System. The materials from which the Axya device is fabricated have an established history of use in medical applications, and devices produced by Axya have undergone appropriate testing and in accordance with applicable FDA guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Azya Medical, Inc.
% Mr. Howard Schrayer
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Beverly, Massachusetts 01915

JUL 11 2007

Re: K070253
Trade/Device Name: Axya™ Suture Welding System and Kit
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) Surgical suture
Regulatory Class: Class II
Product Code: GAT, HCF
Dated: July 11, 2007
Received: August 31, 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) 276-0115. 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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its 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): K070253

Device Name: Axya™ Suture Welding System and Kit

Indications For Use:

The Axya Suture Welding System is indicated for use in securing sutures in soft tissues and for securing ligatures of tubular structures wherever conventional sutures or surgical staples are appropriate. The System may be used in arthroscopic, laparoscopic and open surgical procedures.

Prescription Use____X____ **AND/OR** **Over-The-Counter Use_____**
(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)

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

510(k) Number K070253