NOV 27 1998

K983108

SUMMARY OF SAFETY AND EFFECTIVENESS

This submission supports the position that the Axya Suture Welding System and Kit (SWK) is substantially equivalent in design and function to the Axya Suturing and Ligating System (ASLS) {510(k) K980988] 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 in soft tissue to close either traumatic or surgically produced wounds. The SWK is fabricated from materials with a substantial history of use in medical devices. Both the SWK and the predicate device secure the suture loop with an ultrasonic weld.

The 510(k) Notice for the predicate 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 Suture Welding System because the design and components of the welding mechanism are the same as those used in the ASLS that was 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 synthetic 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 confirm that synthetic monofilament sutures secured by weld formed with the AxyaWeld Tips have equivalent knot strength to sutures welded with the predicate AxyaStitch Cartridge.

In previously submitted efficacy studies of synthetic absorbable sutures (Maxon™), these materials were tested for strength at baseline and at one-week intervals over seven weeks following immersion in a constant temperature bath maintained at 98.5 degrees F. The strength loss curves for this synthetic absorbable suture follow the profile described in the suture manufacturer's package insert and exceed the predicted strength retention requirements based on USP requirements for knot strength of synthetic absorbable suture. This demonstrates that the welding process had no deleterious effect on the strength retention profile of the synthetic absorbable sutures.

The safety of the suture delivery system was evaluated by placing both welded sutures and manually knotted sutures in the dorsal skin and in bowel tissue of New Zealand rabbits. 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 is similar to the energy source used in the UltraCision Harmonic Scalpel [510(k) K895252].

Because of design features of the SWK, 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 Suture Welding 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 Suture Welding 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

NOV 27 1998

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

Re: K983108
Trade Name: Axya, Suture Welding System and Kit, (SWK)
Regulatory Class: II
Product Code: GAW
Dated: September 03, 1998
Received: September 04, 1998

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 (for the indications for use stated in the enclosure) to 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 (the Act). You may, therefore, market your device subject to the general control provisions of the Federal Food, Drug, and Cosmetic Act (Act). Please note: If you purchase your device components in bulk (i.e., unfinished) and further process them (e.g., sterilize), you must submit a new 510(k) before including these components in your **kit/tray**. The general control provisions of the Act include requirements for 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 (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 (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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 for the device. However, you should be aware of the following additional information regarding the inclusion of a suture as a component of your device:

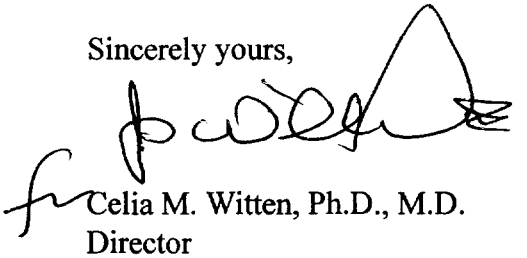
1. The labeling, packaging and method of sterilization of the suture cannot be changed without prior notification, review and clearance by FDA.

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 our 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/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

K983108

510(k) Number (if known):_____

Device Name: Axya, Suture Welding System and Kit, (SWK)

Indications For Use:

The Suture Welding System and Kit is indicated for securing synthetic monofilament sutures in soft tissues and for securing ligatures of tubular structures wherever conventional monofilament sutures or surgical staples are appropriate. The SWK is indicated for use in both traditional open surgery and endoscopic surgical procedures.

(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 Devices
510(k) Number K983108

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)