MAY 1 1 1998

K980988

SUMMARY OF SAFETY AND EFFECTIVENESS

This summary supports the position that the Axya Automatic Suturing and Ligating System (ASLS) is substantially equivalent in design and function to 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 ASLS is fabricated from materials with a substantial history of use in medical devices. Both the ASLS and the predicate device use curved, hollow needles to place the suture through soft tissue structures. The ASLS secures the suture loop with an ultrasonic weld while the predicate device requires that the suture be secured with manually placed knots.

The 510(k) Notice contains summaries of both *in vivo* and *in vitro* studies which were conducted to evaluate the safety, efficacy and appropriatness of the ASLS. Data are presented which demonstrate that sutures placed by means of the ASLS 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. In further 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 ASLS 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 ultrasonic energy source used to weld and secure the suture loop is similar to the energy source used in the UltraCision Harmonic Scalpel [510(k) K895252]. Because of design features of the ASLS, no portion of the ultrasonic generator comes into contact with human tissues. 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 empolyed and no new chemical entities are introduced or produced in the welding process.

The Axya Automatic Suturing and Ligating System is sterilized by exposure to gamma irradiation at 2.5 Mrads which provides a sterility assurance level of at least 10^{-6} or 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. This sterility processes, the manufacturing process, and the packaging process are validated by the manufacturer.

Axya LLC believes that the information provided establishes that similar legally marketed and pre-enactment devices have been used historically for the same types of clinical applications as the Axya Automatic Suturing and Ligating System. 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

MAY 11 1998

Mr. Howard L. Schrayer
Axya Medical, Incorporated
12 South Street
Marblehead, Massachusetts 01945

Re: K980988
Trade Name: Axya Medical Automatic Suturing and Ligating System
Regulatory Class: II
Product Code: GAB and KOG
Dated: March 16, 1998
Received: March 17, 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 (Act). 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 (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 requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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.

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

510(k) Number (if known): K980988

Device Name: Axya, Automatic Suturing and Ligating System, (ASLS)

Indications For Use:

The ASLS is indicated for the placement of synthetic monofilament sutures in soft tissues and for the ligation of tubular structures wherever conventional monofilament sutures or surgical staples are appropriate. The ASLS 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 K980988

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