K021929

SEP 1 0 2002

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: Model 100 Sonic Scalpel™ Ultrasonic Surgical System

Classification: "Ultrasonic Surgical System", Product code: LFL
Class II

Predicate Devices

Ultracision, Inc. (currently marketed by Ethicon, Inc.) Ultrasonic Scalpel [501(k) Number K895252]

Olympus Optical Co. SonoSurg™ System [510(k) Number K972114].

Description

The Sonic Scalpel™ Ultrasonic Surgical System consists of an Ultrasonic Generator / Control Unit, a reusable handpiece that contains the ultrasonic transducer, and a family of disposable cutting / coagulation shears. The Sonic Scalpel™ shears are available with a range of shaft lengths, diameters and blade lengths as single-patient-use, sterile instruments. The shears are coupled to the reusable handpiece by means of a collar. The titanium instrument blade tip consists of one fixed blade and one movable blade. The tip may be rotated to facilitate the surgical approach. The shears are designed for cutting, coagulation and blunt dissection.

Indications

The Axya Model 100 Sonic Scalpel™ Ultrasonic Surgical System is indicated for use in endoscopic and open surgical procedures for the cutting and coagulation of soft tissue structures.

Substantial Equivalence

This submission supports the position that the Axya Model 100 Ultrasonic Surgical System is substantially equivalent to a number of previously cleared devices, including the Ultracision, Inc. (currently marketed by Ethicon, Inc.) Ultrasonic Scalpel [501(k) Number K895252] and the Olympus Optical Co. SonoSurg™ System [510(k) Number K972114]. These systems are designed, manufactured and tested to meet the requirements of IEC 601-1, IEC 601-1-2, CISPR11 and UL2601-1.

The 510(k) Notice contains summaries of *in vitro* studies that were conducted to evaluate the shears blade excursion (amplitude) at various power settings and the blade temperature over a range of operating conditions.

The data presented demonstrate that the blade amplitude and temperature range of the Axya Model 100 Sonic Scalpel Ultrasonic Surgical System is comparable to those parameters for the predicate Ultracision device.

The Notice contains a summary report of an in vivo study that evaluated the efficacy of the Ultrasonic Surgical System in laboratory animals. The results of this testing indicate that the system produces results similar to the performance of typical electrosurgical systems.

The single-patient-use shears component of the Ultrasonic Surgical System is provided sterile.

Axya Medical, Inc. believes that the information provided establishes that similar legally marketed systems have been used for the same clinical applications as the Axya Model 100 Ultrasonic Surgical System. The materials from which the Axya device is fabricated have an established history of use in medical applications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 0 2002

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

Re: K021929
Trade/Device Name: Axya, Model 100 Sonic Scalpel™ Ultrasonic Surgical System
Regulatory Class: Unclassified
Product Code: LFL
Dated: June 11, 2002
Received: June 12, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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 Part 807.97). 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, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K021929

Device Name: Axya, Model 100 Sonic Scalpel™ Ultrasonic Surgical System

Indications For Use:

The Axya Model 100 Sonic Scalpel™ Ultrasonic Surgical System is indicated for use in endoscopic and open surgical procedures for the cutting and coagulation of soft tissue structures.

(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 K021929

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

(Optional Format 1-2-96)