K980617

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Appendix II

Summary of Safety and Effectiveness

Richard-Allan's Reflex AEC 35, with shorter shaft length is substantially equivalent to our currently marketed Reflex AEC 35. These instruments have the same component materials, method of manufacturing, and method of sterilization. These instruments have similar instructions for use.

This difference in shaft lengths will not affect safety or effectiveness of our device, overall function or application intended for the use of this type of device.

Richard-Allan's Reflex AEC 35 has the same intended use as our current Reflex AEC 35, Multifire GIA, and Endo GIA 30. These instruments are intended to achieve hemostatic transection of vessels and other tissue structures.

Richard-Allan's current Reflex AEC 35 is intended for use in a variety of laparoscopic, endoscopic, and gynecologic procedures. The Auto Suture Multifire GIA is intended for open abdominal, gynecologic, pediatric, and thoracic procedures. The Endo GIA 30 is intended for use in abdominal, gynecologic, pediatric, and thoracic endoscopic procedures.

The *expanded indication* for use of the Richard-Allan current and modified, shorter shaft instruments is for general open procedures, such as abdominal, thoracic, pediatric, gynecologic, etc. This difference in indications for use will not affect safety or effectiveness of our device, or overall function of this type of device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 1998

Ms. Julie Powell
Quality Assurance & Regulatory Affairs Director
Urohealth Systems Incorporated
Richard-Allan Medical Industries
8850 M-89
Richland, Michigan 49083

Re: K980617
Trade Name: Reflex AEC Linear Stapler/Cutter
Regulatory Class: II
Product Code: GDW
Dated: June 17, 1997
Received: January 23, 1998

Dear Ms. Powell:

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,

for 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): K980617

Device Name: Reflex AEC

Indications for Use:

For use in a variety of open procedures, such as abdominal, pediatric, thoracic, gynecologic, etc. and for use in endoscopic and laparoscopic procedures to achieve hemostatic transection of vessels and other 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 Devices
510(k) Number K980617

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

(Optional Format 1-2-96)