

JUN 29 1999

**AMERICAN MEDICAL SYSTEMS****510(k) SUMMARY****I. SUBMITTER**

*Name and Address:* American Medical Systems, Inc.  
10700 Bren Road West  
Minnetonka, MN 55343 USA

*Establishment Registration Number:* 2183959

*Contact Person:* David Worrell

*Date of Summary Preparation:* April 15, 1999

**II. MANUFACTURER**

*Name and Address:* American Medical Systems  
10700 Bren Road West  
Minnetonka, MN 55343-9679

*Establishment Registration Number* 2183959

**III. DEVICE NAME**

*Device Common or Usual Name:* Resection Loop or Resection  
Electrode

*Device Trade Name:* AMS Coaguloop™ Resection  
Electrode

*Classification Name:* Endoscopic electrosurgical unit with  
accessories (21 CFR 876.4300)

#### **IV. DEVICE DESCRIPTION**

The AMS Coaguloop™ Resection Electrode is an electrosurgical device designed for use with commercially available resectoscopes and general purpose monopolar electrosurgical generators. The Coaguloop™ Resection Electrode is designed to remove and coagulate soft tissue by means of radio frequency electrical current.

#### **V. INDICATION FOR USE**

The Coaguloop™ Resection Electrode is intended to be used for resection, ablation, and fulguration in the prostate gland and the bladder.

#### **VI. SUBSTANTIAL EQUIVALENCE SUPPORT**

American Medical Systems' Coaguloop™ Resection Electrode is similar in indications, design, and features to various resectoscope electrodes that are in commercial distribution. The predicate devices that AMS is claiming substantial equivalence to are the AMS Coaguloop™ Resection Electrode K971512 and the Circon/ACMI Vaportome™ Resection Loop Electrode K973820.

#### **VII. STERILIZATION METHODOLOGY**

Sterilization is based on the recommendations in ANSI/AAMI and ISO 11137 Guideline for the Sterilization of health care products - Requirements for validation and routine control - Radiation sterilization. The devices are terminally sterilized by exposure to gamma radiation. This gamma radiation sterilization cycle will achieve a minimum Sterility Assurance Level (SAL) of  $10^{-6}$ .

#### **VIII. -BIOCOMPATIBILITY**

Biocompatibility testing generally followed the recommendations of FDA Blue Book Memorandum #G95-1 entitled "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing."

#### **CONCLUSION**

In summary, the data and information provided within this 510(k) Premarket Notification adequately support that the AMS Coaguloop™ Resection Electrode is substantially equivalent to the AMS Coaguloop™ Resection Electrode K971512 and the Circon/ACMI Vaportome™ Resection Loop Electrode K973820.



JUN 29 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Mr. David Worrell  
Regulatory Affairs Specialist  
American Medical Systems, Inc.  
10700 Bren Road West  
Minnetonka, MN 55343Re: K991314  
AMS Coaguloop™ Resection Electrode  
Dated: April 15, 1999  
Received: April 16, 1999  
Regulatory Class: II  
21 CFR §876.4300/Procode: 78 FAS

Dear Mr. Worrell:

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 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). 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 requirements, 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) 594-4613. 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/dsma/dsmamain.html>".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.  
Acting Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if Known): \_\_\_\_\_

Device Name:           AMS Coaguloop™ Resection Electrode

Indications For Use:

The AMS Coaguloop™ Resection Electrode is intended to be used for resection, ablation, and fulguration in the prostate gland and the bladder.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

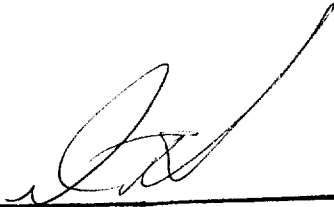
---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K991314