K991314

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)

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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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 1999

Mr. David Worrell
Regulatory Affairs Specialist
American Medical Systems, Inc.
10700 Bren Road West
Minnetonka, MN 55343

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

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