American Medical Systems, Inc.
Pfizer Hospital Products Group
10700 Bren Road West
Minnetonka, MN 55343
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American Medical Systems

SUMMARY OF SAFETY AND EFFECTIVENESS

I. SUBMITTER

JUL 24 1997

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

Establishment Registration Number: 2183959

Contact Person: John M. Otto

Date of Summary Preparation: April 25, 1997

II. MANUFACTURER

Name and Address: Pemstar, Inc.
2535 Highway 14 West
Rochester, MN 55901 USA

Establishment Registration Number: 2133786

III. DEVICE NAME

Device Common or Usual Name: Unit, Electrosurgical, Endoscopic (With or Without Accessories)

Device Trade Name: AMS Coaguloop™ Resection Electrode

IV. PREDICATE DEVICE

Olympus™ Resectoscope Loop Electrode K903323

V. DEVICE DESCRIPTION

The Coaguloop™ consists of either a single or double conductor. The conductor(s) either form or are in electrical communication with a cutting loop that is designed to concentrate the current and cut and coagulate soft tissue as it is drawn along. The grooves at the tip of the electrode are designed with the intent to further enhance the current density at the tip of the grooves. This allows for cutting, and the utilization of the larger surface area on the underside of the grooves and loop, which generates the heat required for the coagulation of resected tissue.

The AMS Coaguloop™ Resection Electrode is designed for use in several resectoscope designs with general purpose monopolar electrosurgical generators. The AMS Coaguloop™ Resection Electrode is manufactured in four (4) configurations designed for use with the following manufactured resectoscopes: Storz™, Circon/ACMI™, Olympus™, and Richard Wolf™. The components of each configuration follows:

VI. INDICATION FOR USE

The AMS Coaguloop™ Resection Electrode has the same intended use as the Olympus™ Resectoscope Loop Electrode. These products are intended to be used for the resection, ablation, and fulguration of soft tissue.

VII. COMPARISON TO PEDICATE DEVICE

American Medical Systems' Coaguloop™ Resection Electrode is similar in indications, design, and features to various resectoscope electrodes that are in commercial distribution. The predicate device that AMS is claiming substantial equivalence to is the Olympus™ Resectoscope Loop Electrode (K903323).

a. Intended Use

The AMS Coaguloop™ Resection Electrode has the same intended use as the Olympus™ Resectoscope Loop Electrode. These products are intended to be used for the resection, ablation, and fulguration of soft tissue.

b. Principles of Operation

The basic principle of the function of the Coaguloop™ resection electrode involves developing a circuit consisting of a power generator and an active electrical circuit.

The power generator is the source of electron flow and voltage. The active electrical circuit is composed of the generator , the active resecting electrode, the patient, and the patient return electrode (grounding pad).

The electrode or loop acts as an antenna which transmits electrical current (power in Watts/cm^2) of a specific wave form from the generator in a range from 500 KHz - 3.3 MHz (Radio Frequency range).

The natural impedance of living tissue provides heat build-up in the tissues as the electron flow through the electrode overcomes the tissue impedance. When the electrode is brought into contact with the tissue, effectively completing the circuit, and power is applied, current builds along the cutting element of the electrode until the tissue impedance is overcome and energy arcs from the loop to the tissue. This produces intense heat and subsequent tissue vaporization along the cut line. This arching produces maximum current concentration at the cut site.

c. Device Performance

Resectoscope electrodes have an extensive history of use in the medical device community. The Coaguloop™ device, and other manufacturer's resectoscope electrodes, are manufactured from materials that are widely used in the medical device industry. The materials have undergone extensive biocompatibility testing. The devices are manufactured primarily of Molybdenum.

All components are manufactured using rigid conformance standards to ensure the safe and effective performance of the finished product. Frequent, detailed quality checks are carried out at each phase of the assembly process to verify that only those units meeting all parameters are released for sale. Table 1 on the folowing page provides a comparison of the proposed device to the predicate device.

d. Bench Testing

The following tests were performed to demonstrate electrode reliability and adherence to performance specifications:

a. Fit Test
b. Destructive Test
c. Biocompatibility Test
d. Dielectric/Continuity Test
e. Metallurgical Analysis
f. Loop Area Calculations
g. Animal Test
h. Coaguloop - Histopathology Analysis of Lapine and Canine Tissue Samples
i. Current Distribution Test
j. Packaging Test I
k. Packaging Test II

The results of the testing determined that the elctrodes performed per specification.

In summary, American Medical Systems has provided information within this 510(k) Premarket Notification to indicate that the AMS Coaguloop™ Resection Electrode is safe and effective for its intended use (for the resection, ablation, and fulguration of soft tissue). Additionally, the AMS Coaguloop™ Resection Electrode has been shown to be comparable in terms of intended use and technological characteristics to the Olympus™ Resectoscope Loop Electrode which has been cleared for commercial distribution. The data and information provided within this 510(k) Premarket Notification adequately support that the Coaguloop™ Resection Electrode is substantially equivalent to the Olympus™ Resectoscope Loop Electrode.

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TABLE 1

COMPARISON OF PROPOSED DEVICE TO PREDICATE DEVICE

Use and Feature	AMS Coaguloop™ Resection Electrode	Olympus™ Resectoscope Loop Electrode
Intended Use	To resect, ablate, and fulgurate soft tissue.	To resect, ablate, and fulgurate soft tissue.
Mode of Operation	Electrocautery current conducted through loop allows fulguration or cutting by the surgeon	Electrocautery current conducted through loop allows fulguration or cutting by the surgeon
Application	1. Device to be utilized in conjunction with and as an accessory to a standard endoscopic electroscope. 2. Standard electro-surgical power source is used for the current generation through the electrode.	1. Device to be utilized in conjunction with and as an accessory to a standard endoscopic electroscope. 2. Standard electro-surgical power source is used for the current generation through the electrode.
Material	Tungsten/Molybdenum wire insulated with non-conducting shrink wrap.	Tungsten wire insulated with non-conducting shrink wrap.
Design	Flat loop with multiple shallow grooves.	A circular loop
Sterility	The electrode is delivered sterile and is designed for single-use only. The device is sterilized by Gamma radiation	Sterile/disposable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 24 1997

Mr. John M. Otto
Senior Regulatory Affairs Associate
American Medical Systems, Inc.
Pfizer Hospital Products Group
10700 Bren Road West
Minnetonka, Minnesota 55343

Re: K971512
AMS Coaguloop™ Resection Electrode
Dated: April 25, 1997
Received: April 28, 1997
Regulatory class: II
21 CFR §876.4300/Product code: 78 FAS

Dear Mr. Otto:

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) 594-4613. 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/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
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): K971512

Device Name: _AMS Coaguloop™ Resection Electrode_____

Indications For Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert A Sullivan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971512

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

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