American Medical Systems, Inc.
Pfizer Hospital Products Group
10700 Bren Road West
Minnetonka, MN 55343
Tel 612 933 4666 Fax 612 930 6592
Toll Free 800 328 3881

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K972091

American Medical Systems

AUG 29 1997

SUMMARY OF SAFETY AND EFFECTIVENESS

I. SUBMITTER

Name and Address:	American Medical Systems, Inc. 10700 Bren Road West Minnetonka, MN 55343
Contact Person:	Lisa L Pritchard
Date of Summary Preparation:	June 2, 1997
Establishment Registration Number:	2183959

II. DEVICE NAME

Device Common or Usual Name:	Foreign Body Extractor
Device Trade Name:	AMS Foreign Body Extractor

III. PREDICATE DEVICE

Gastroenterology-Urology Biopsy Instrument

IV. DEVICE DESCRIPTION

The AMS Foreign Body Extractor is made of stainless steel and consists of an obturator, sheath, grasper, seals, handle, security clip, telescope stabilizers and ACMI adaptor ring. The AMS Foreign Body Extractor Accessory Kit contains replacement security clip, telescope stabilizers, ACMI adaptor ring, and seals. To facilitate insertion into the urethra and bladder, the obturator is placed inside the sheath. Once inside the bladder, the obturator is removed and the grasper is placed within the lumen of the sheath. The handle is then attached and the telescope inserted into the sheath. The grasping jaws are operated by moving the handle to open and close the grasping jaws to capture and remove the foreign body.

V. INDICATION FOR USE

The AMS Foreign Body Extractor is intended for use in the removal of a foreign body from the bladder under direct vision.

VI. COMPARISON TO PREDICATE DEVICE

The AMS Foreign Body Extractor is substantially equivalent to the Richard Wolf 8393 Modular Biopsy Forceps and the Richard Wolf series 8962 Rigid Forceps with Alligator Jaws which are in commercial distribution.

a. Intended Use

The AMS Foreign Body Extractor is intended to remove a foreign body from the bladder under direct vision. The Richard Wolf 8393 series modular biopsy forceps are used for removal of tissue for biopsy. The Richard Wolf Rigid Forceps with alligator jaws are intended for the percutaneous removal of kidney stones.

b. Principles of Operation

The AMS Foreign Body Extractor utilizes a grasper operated by handle grips to grasp foreign bodies, retract within a sheath and subsequently remove from the bladder. The Richard Wolf series 8393 modular forceps similarly utilize a grasper which is operated by handle grips to transurethrally grasp and subsequently remove material. The Richard Wolf 8962 Rigid forceps with alligator jaws utilize a similar grasper which is manipulated by handle grips to grasp and remove stones from the kidneys.

c. Device Performance

The AMS Foreign Body Extractor is manufactured primarily from stainless steel, which is widely used in the medical device industry. The material has previously undergone biocompatibility testing.

All components are verified to ensure that only those meeting all parameters are released for sale.

The Richard Wolf series 8393 modular forceps and the Richard Wolf rigid forceps with alligator jaws both utilize stainless steel in the functional components of the tools.

d. Bench Testing

American Medical Systems has provided descriptive data on the test plan and test results for the Foreign Body Extractor. These data support that the function and characteristics of the device are suitable for its intended use.

In summary, American Medical Systems has provided information within the 510(k) Premarket Notification to indicate that the Foreign Body Extractor is safe and effective for its intended use in the removal of foreign bodies from the bladder. Additionally, the Foreign Body Extractor has been shown to be comparable in terms of intended use and technological characteristics to biopsy forceps currently in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 29 1997

Ms. Ginger Sackett Glaser
Regulatory Affairs Specialist
American Medical Systems, Inc.
Pfizer Hospital Products Group
10700 Bren Road West
Minnetonka, Minnesota 55343

Re: K972091
AMS Foreign Body Extractor
Dated: August 21, 1997
Received: August 22, 1997
Regulatory class: II
21 CFR §876.4680/Product code: 78 FFL

Dear Ms. Glaser:

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): K972091

Device Name: AMS Foreign Body Extractor

Indications for Use:

The AMS Foreign Body Extractor is intended for use in the removal of a foreign body from the bladder under direct vision.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Watkins

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972091

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)