# 510(k) Summary of Safety and Effectiveness
# ACMI Corporation
# ACMI® MR-6A/MR-6LA Autoclavable Ureteroscopes

K052044
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## General Information

| | |
|---|---|
| Manufacturer: | ACMI Corporation<br>136 Turnpike Rd.<br>Southborough, MA 01772-2104 |
| Establishment Registration Number: | 2020483 |
| Contact Person: | Terrence E. Sullivan<br>Director, Regulatory Affairs |
| Date Prepared: | July 26, 2005 |

## Device Description

| | |
|---|---|
| Classification Name: | Endoscope and accessories<br>(21 CFR 876.1500), Class II<br>Gastroenterology/Urology Panel |
| Trade Name: | ACMI® MR-6A/MR-6LA Autoclavable Ureteroscopes |
| Generic/Common Name: | Endoscope and accessories |

## Predicate Device

| | |
|---|---|
| ACMI® MR-Series Ureteroscopes | K011849 |

## Intended Uses

The ACMI® MR-6A/MR-6LA Autoclavable Ureteroscopes (MR-6A) are intended for the examination/operation of the urinary tract, and using additional accessories, to perform various diagnostic and therapeutic procedures. These devices are marketed as reusable devices; methods for cleaning, disinfecting and sterilization are included in latter sections of this submission under Section 7.0, "Cleaning, Disinfection, and Sterilization".

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## Product Description

Like the predicate ACMI® MR-Series Ureteroscopes, the ACMI® MR-6A/MR-6LA Autoclavable Ureteroscopes are semi-rigid endoscopes with two working channels. Flexible accessories such as stone baskets, retrievers, forceps, electrohydraulic lithotripter probes and laser fibers may be used through either working channel.

The main component parts of each device include:

1. The metal shaft
2. Two working channels
3. An eyepiece
4. Optical imaging fibers
5. Light guide connector post
6. A distal lens
7. Light carrier fibers

This Special 510(k) proposes the addition of autoclaving processes as a sterilization method, a change in shaft material from stainless steel to MP35N alloy, as well as a change in the manufacturing process to allow the shaft to be hermetically sealed using a micro-TIG and laser welding process in place of epoxy seals. The indications for use, principles of operation, overall length, working channel length and working channel inner diameters of the ACMI® MR-6A/MR-6LA Autoclavable Ureteroscopes remain the same or essentially the same as the predicate device.

## Summary of Safety and Effectiveness

The proposed modifications for the ACMI® MR-6A/MR-6LA Autoclavable Ureteroscopes, as described in this submission, are substantially equivalent to the predicate device. The proposed addition of autoclaving as a recommended sterilization process and change in shaft modification in design specifications, performance specifications, and dimensional specifications are not substantial changes or modifications, and do not significantly affect the safety or efficacy of the devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2005

Mr. Terrence E. Sullivan
Director, Regulatory Affairs
ACMI Corporation
136 Turnpike Road
SOUTHBOROUGH MA 01772

Re: K052044
Trade/Device Name: ACMI® MR-6A/MR-6LA Autoclavable Ureteroscopes
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Dated: July 26, 2005
Received: July 28, 2005

Dear Mr. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

**Device Name:** ACMI® MR-6A/MR-6LA Autoclavable Ureteroscopes

**510(k) Number:** K052044

**Indications for use:**

The ACMI® MR-6A/MR-6LA Autoclavable Ureteroscopes are intended for the examination/operation of the urinary tract, and using additional accessories, to perform various diagnostic and therapeutic procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: __ X __ **OR** Over-the-Counter Use: _____

(Per 21 CFR 801.109)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052044