SEP - 2 2003

K031758

510(k) Summary of Safety and Effectiveness
ACMI Corporation
ACMI® M4™ Telescope
(Page 1 of 2)

General Information

Manufacturer:	ACMI Corporation 136 Turnpike Rd. Southborough, MA. 01772-2104
FDA Establishment Registration:	2020483
Contact Person:	Gabriel J. Muraca, Jr. Senior Regulatory Affairs Specialist
Date Prepared:	June 3, 2003

Device Description

Trade Name: ACMI® M4™ Series Telescopes

ACMI M4 Series Telescopes are optical devices that are used with endoscopic accessories in diagnostic and surgical procedures of the urological and gynecological systems.

Classification Names:

21CFR 876.1500 - Endoscope and accessories and
21 CFR 884.1690 – Hysteroscope and accessories

Generic/Common Name:

Telescopic system used along with endoscopic accessories in diagnostic and surgical procedures of the urological and gynecological systems.

Predicate Devices

ACMI Resectoscope System and accessories	K890328/B

Intended Uses

ACMI M4 Series Telescopes are intended for use in patients requiring endoscopic evaluation or for surgical procedures of the urological or gynecological systems.

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Product Description

ACMI M4 Telescopes are optical devices that are used along with endoscopic accessories for diagnostic and therapeutic procedures in urology and gynecology. They are designed to be inserted through an endoscopic device such as an ACMI cystourethroscope, hysteroscope, or resectoscope. M4 Telescopes are (4mm diameter, 31 cm long) rigid autoclavable optical instruments available in four directions of view: M4-0A, direct (0°), M4-12A, operative (12°), M4-30A, foroblique (30°), and M4-70A, lateral (70°), to assist the physician in visualization of the anatomy during diagnostic and surgical procedures.

Technological Characteristics and Substantial Equivalence

The M4 Series Telescopes are substantially equivalent to features incorporated in the M2 and M3 telescopes, as described in K890328/B, the ACMI Resectoscope System and accessories. The M2 and M3 telescopes are legally marketed predicate devices. The M4 Series designs utilize similar telescope technology (design, materials, and performance specifications) as in the predicate devices and, therefore, are substantially equivalent to the ACMI M2 and M3 series telescopes.

Summary of Safety and Effectiveness

This 510(k) proposes several modifications in materials, design, and the manufacturing process for the M4 Series telescopes. The indications for use and principles of operation remain the same as in the predicate devices. The proposed modifications for the M4 Series Telescopes, as described in this submission, are substantially equivalent to the predicate devices. The proposed modification in materials, design, and processing are not substantial changes or modifications, and do not significantly affect the safety or efficacy of the devices.

In summary, ACMI believes the ACMI M4 Series telescopes are substantially equivalent to the predicate devices, because they have the same intended use and similar technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 2 2003

Mr. Gabriel J. Muraca, Jr., RAC
Senior Regulatory Affairs Specialist
ACMI Corporation
136 Turnpike Road
SOUTHBOROUGH MA 01772-2104

Re: K031758
Trade/Device Name: ACMI® M4™ Telescopes
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 FBP
Dated: June 3, 2003
Received: June 6, 2003

Dear Mr. Muraca:

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 (PMA), it may be subject to 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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® M4™ Telescope**

510(k) Number: K031758

Indications for Use:

ACMI® M4™ Series Telescopes are intended for use in patients requiring endoscopic evaluation or for surgical procedures of the urological or gynecological systems.

(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 K031758