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SECTION 10

510(k) SUMMARY
ACMI ECN Video Cystonephroscope

1. Sponsor: ACMI Corporation
136 Turnpike Road
Southborough, MA 01771-2104

Contact: Frank J. Fucile.
Telephone: 508-804-2632
Date: March 25, 2003

2. Device Name:

Proprietary Name:	ACMI ECN Video CystoNephroscope System
Common/Usual Name:	Endoscope, Video Camera and accessories
Classification Name:	Endoscope, Surgical Camera and accessories

2. Predicate Devices:

ACMI USA Series™ ACN™-2 Flexible CystoNephroscope (K904797)

ACMI USA Series™ APN™ -2 Flexible Choledochoscope (K012951)

Dyonics Vision 111 Mobile Video Unit, Smith & Nephew, Inc., (K010489)

Visera Cystovideoscope, Olympus (K020174)

Pentax ECY-1530 Video Choledoconephroscope, Pentax America,
(probably covered under K951191 and internal letter to file adding video)

3. Device Description:

The ECN Video Cystonephroscope is a flexible endoscope that incorporates video sensor technology to capture the endoscopic image, replacing the fiber optic image bundle typically used in most endoscopes. The ECN Video Cystonephroscope can be introduced either through the urethra into the bladder or through a percutaneous tract into the abdominal cavity or kidney

4. Intended Use:

The ACMI Electronic Video CystoNephroscope (ECN) System is a flexible endoscopic surgical video system consisting of an endoscope with a CMOS video sensor and light source mounted in the endoscope, and a Controller unit. This system is intended for use to examine body cavities, hollow organs and canals in the body, in the urinary tract, and can be used percutaneously to examine the interior of the kidney; and, using additional accessories, can be used to perform various diagnostic and therapeutic procedures

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5. Technological Characteristics and Substantial Equivalence:

The ECN Flexible Video Cystonephroscope is substantially equivalent to features incorporated into the following legally marketed predicate devices:

The ECN Flexible Video Cystonephroscope utilizes the flexible endoscope technology (design and materials) of the following ACMI flexible endoscopes:

- **ACMI USA Series™ ACN-2** Flexible CystoNephroscope (K904797)
- **ACMI USA Series™ APN -2** Flexible Choledochoscope (K012951)

The ECN Flexible Video Cystonephroscope incorporates the video sensor technology located in the distal tip of the endoscope similar to that utilized in the following devices:

- **Visera Cystovideoscope** CYF Type V/VA, **Olympus America, Inc.**, (K021074)
- **Pentax ECY-1530** Video Choledoconephroscope, **Pentax America**, (probably covered under K951191 and internal letter to file adding video)

The ECN Flexible Video Cystonephroscope incorporates the CMOS sensor technology similar to that used in the **Dyonics** Vision 111 Mobile Video Unit, **Smith & Nephew, Inc.**, (K010489).

Finally, the ECN Flexible Video Cystonephroscope uses video processing technology (hardware and software) similar to that used in the **ACMI MicroDigital® IP 6.2 Controller** (510K exempt).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2003

Mr. John A. DeLucia
VP, QA/RA/CA
ACMI Corporation
136 Turnpike Road
SOUTHBOROUGH MA 01772

Re: K030960
Trade/Device Name: ACMI® Electronic Video CystoNephroscope (ECN) System
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Product Codes: 78 FAJ and FGA
Regulation Number: 21 CFR §878.4160
Regulation Name: Surgical camera and accessories
Product Code: 80 FWF
Dated: June 25, 2003
Received: June 27, 2003

Dear Mr. DeLucia:

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

SECTION 8

K030960

Indications for Use Statement

510(k) Number (if known): K030960

Device Name: ACMI® Electronic Video CystoNephroscope (ECN) System

Indications For Use:

The ACMI Electronic Video CystoNephroscope (ECN) System is a flexible endoscopic surgical video system consisting of an endoscope, CMOS video sensor and light source mounted in the endoscope, and a Controller unit. This system is intended for use to examine body cavities, hollow organs and canals in the body, in the urinary tract, and can be used percutaneously to examine the interior of the kidney; and, using additional accessories, can be used to perform various diagnostic and therapeutic procedures

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

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 K030960