K023358

JAN 03 2003

510(k) Summary for the ACMI USA Series™ DUR™-8 and DUR™-8 Elite Flexible Ureteropyeloscope and Choledochoscope

1. Sponsor

ACMI Corporation
136 Turnpike Road
Southborough, MA 01771-2104

Contact Person: Terrence E. Sullivan
Telephone: 508-804-2739
Date Prepared: October 4, 2002

2. Device Name

Proprietary Name:	ACMI Corporation USA Series™ DUR™-8 and DUR™-8 Elite Flexible Ureteropyeloscope and Choledochoscope
Common/Usual Name:	Flexible endoscope
Classification Name:	Endoscope and accessories

3. Predicate Devices

- ACMI APN™-2 (K012951)
- Karl Storz MVM 7.5 Fr. Flexible Choledochoscope (K972926)
- Karl Storz 15.5 Fr. Flexible Choledocho-Fiberscope (K971977)
- ACMI DUR™-8 (K012925)

4. Device Description

Both the DUR™-8 and DUR™-8E are non-sterile, reusable flexible fiberoptic endoscopes. They feature a lubricious polyurethane outer covering, a patented cable compensation system, a patented torque-stabilization shaft construction, duel light transmission, a rotating light post, luer lock irrigation and biopsy ports, and a detachable light guide. The optics, illumination carriers, working channel, manufacturing methods and specifications of both devices are identical.

The DUR™-8E is a modification of the DUR™-8 designed to provide the clinician with greater control over the distal tip of the endoscope. The DUR™-8 has a passive deflection section, while the DUR™-8 Elite has an actively controllable

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section proximal to the primary active deflection section. A secondary deflection control lever has been added to the head of the DUR™-8 Elite.

5. Intended Use

The ACMI USA Series™ DUR™-8 and DUR™-8 Elite (DUR™-8E) Flexible Ureteropyeloscope and Choledochoscope are indicated for therapeutic and diagnostic procedures in the entire intrarenal collecting system and are also indicated for the examination of bile ducts, and using additional accessories, to perform various diagnostic and therapeutic procedures during cholecystectomy.

6. Technological Characteristics and Substantial Equivalence

ACMI Corporation bases the claim of equivalence on similarities in indications for use, design, materials, technological characteristics, and operational characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 03 2003

Mr. Terrence Sullivan
Corporate Quality Systems Manager
ACMI Corporation
136 Turnpike Road
SOUTHBOROUGH MA 01772

Re: K023358
Trade/Device Name: USA Series™ DUR-8™ Elite and USA Series DUR™-8
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 FGB and FBN
Dated: October 4, 2002
Received: October 7, 2002

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 (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 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:

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" (21 CFR Part 807.97). 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

Indications for Use Statement

510(k) Number (if known): K023358

Device Name: ACMI USA Series™ DUR™-8 and DUR™-8 Elite (DUR™-8E) Flexible Ureteropyeloscope and Choledochoscope

Indications For Use:

The ACMI USA Series™ DUR™-8 and DUR™-8 Elite (DUR™-8E) Flexible Ureteropyeloscope and Choledochoscope are indicated for therapeutic and diagnostic procedures in the entire intrarenal collecting system. The DUR™-8 and DUR™-8E are also indicated for the examination of bile ducts, and using additional accessories, to perform various diagnostic and therapeutic procedures during cholecystectomy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023358

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