510(k) Summary of Safety and Effectiveness
ACMI Corporation
Dual Lumen Catheter

K043581
B/P3

General Information

Manufacturer:	ACMI Corporation 136 Turnpike Rd. Southborough, MA 01772-2104
Establishment Registration Number:	2020483
Contact Person:	Graham A.L. Baillie Senior Regulatory Affairs Specialist
Date Prepared:	December 27, 2004

Device Description

Classification Name:	Urological catheter and accessories (21 CFR 876.5130), Class II
Trade Name:	Dual Lumen Catheter
Generic/Common Name:	Ureteral Catheter

Predicate Device

Ureteral Catheter	K930483

(The Flexible Tip (open or closed) Ureteral Catheter)

Intended Uses

Dual Lumen Catheter has multiple uses, including ureteral dilation, anesthetic injection, stone displacement, contrast injection, and safe wire/guidewire placement.

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Product Description

Like the predicate Flexible Tip (open or closed) Ureteral Catheter, the Dual Lumen Catheter is a ureteral catheter with a flexible tip used for guidewire placement and for contrast injection.

The Dual Lumen Catheter incorporates the same technological characteristics as the predicate device. The proposed Dual Lumen Catheter raises no new questions of safety or effectiveness. Biocompatibility testing confirms that the different materials of construction (from polyurethane to polyethylene) present no new safety concerns. The method of manufacture (extrusion) is the same for both the predicate and the proposed device. The new material used in the Dual Lumen Catheter has been used in other legally marketed devices within the same classification regulation for the same intended use and has had an established history of successful clinical application in Urology.

Like the predicate device, the Dual Lumen Catheter features a hollow plastic tube placed inside the ureter, which, as in the predicate device, allows for the passage of guidewires and for the injection of fluid. Both catheters are fitted with female luer lock Tuohy-Borst adaptors, and feature soft tips to ensure protection of tissue during passage.

This Special 510(k) proposes an addition of the second lumen to the catheter, a modification of the material characteristics, shortening of the working length and a change of color of the device. The indications for use, principles of operation, and diameter of the Dual Lumen Catheter remain the same as in the predicate device.

Dual Lumen Catheter
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Summary of Safety and Effectiveness

The proposed modifications for the Dual Lumen Catheter, as described in this submission, are substantially equivalent to the predicate device. The proposed 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 device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 - 2005

Mr. Graham Baillie
Quality Assurance Manager
ACMI Corporation
3037 Mt. Pleasant Street
RACINE WI 53404

Re: K043581
Trade/Device Name: Dual Lumen Catheter
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: 78 EYB
Dated: December 27, 2004
Received: December 28, 2004

Dear Mr. Baillie:

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 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

Dual Lumen Catheter
ACMI Corporation
136 Turnpike Road
Southborough, MA 01772

Device Name: Dual Lumen Catheter

510(k) Number: K043581

Indications for use:

The dual lumen ureteral catheter is designed for percutaneous and transurethral access and is indicated as a conduit for multiple uses including, but not limited to, ureteral dilation, stone displacement, delivery of contrast material/anesthetic agents and guidewire placement.

(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)

David A. Lyon

(Division **Sign-Off**)
Division **of Reproductive**, Abdominal
and **Radiological Devices**
510(k) **Number** K043581