510(k) Summary of Safety and Effectiveness
ACMI Corporation
ACMI® DUR-HL Laser Systems

MAY 25 2006

General Information

Manufacturer:	ACMI Corporation 136 Turnpike Rd. Southborough, MA 01772-2104
Contact Person:	Lorraine Calzetta Regulatory Affairs Tel. #: 508-804-2752 Fax #: 508-804-2624
Date Prepared:	March 16, 2006

Device Description

Classification Name:	Class II (21 CR 878. 4810) Laser surgical instrument for use in general and plastic surgery and in dermatology
Trade Name:	ACMI® DUR-HL Laser Systems
Generic/Common Name:	Laser, Holmium YAG, Surgical

Predicate Devices

WaveLight Auriga Laser	K051399
Dornier Medilas H Laser Systems	K983963

Intended Uses

The **ACMI® DUR-HL Laser Systems** are intended to be used in surgical procedures involving open and endoscopic (laparoscopic, hysteroscopic, bronchoscopic, gastroenteroscopic and colonoscopic) breaking up stones, cutting (for example, strictures), ablation, vaporization, excision, incision and coagulation of tissue in the specialties as Urology, Pulmonology, Arthroscopy, Gastroenteroology, Gynecology, ENT (for example, DCR), Lithotripsy, Orthopedics, Discectomy and General Surgery.

Product Description

The **ACMI® DUR-HL Laser Systems** are pulsed solid-state Holmium YAG Lasers with a wavelength of approximately 2080 nm (2.1um). This wavelength is absorbed primarily by water, whereby an average penetration depth of approx. 400 µm (0.4 mm). The lasers are Class IV lasers pursuant to 21CFR 1040 and designed to comply with the requirements outlined in 21 CFR 1040. The **ACMI® DUR-HL Laser Systems** are comprised of the following components:

- Laser Unit, which includes Laser console, control and display panel
- Fiber port for delivery systems
- System microprocessor control electronics
- Covered footswitch
- Operating software
- (For use with) a variety of fiber optic delivery devices/accessories.

Technological Characteristics and Substantial Equivalence

The ACMI® DUR-HL Laser Systems utilize features such as indications for use, design, materials, technological characteristics, and operational characteristics incorporated into the following legally marketed predicate devices:

WaveLight Auriga cleared under K051399
Dornier Medilas H Laser Systems cleared under K983963

In summary, the ACMI® DUR-HL Laser Systems are substantially equivalent to the predicate devices and present no new questions of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2006

ACMI Corporation.
% Ms. Lorraine Calzetta
Regulatory Affairs
136 Turnpike Road
Southborough, Massachusetts 01772-2104

Re: K060752
Trade/Device Name: ACMI® DUR-HL Laser Systems
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 16, 2006
Received: March 21, 2006

Dear Ms. Calzetta:

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.

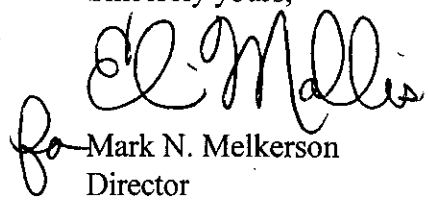
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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 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,



for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: ACMI® DUR-HL Laser Systems

510(k) Number: K060752

Indications for use:

The **ACMI® DUR-HL Laser Systems** are intended to be used in surgical procedures involving open and endoscopic (laparoscopic, hysteroscopic, bronchoscopic, gastroenteroscopic and colonoscopic) breaking up stones, cutting (for example, strictures), ablation, vaporization, excision, incision and coagulation of tissue in the specialties as Urology, Pulmonology, Arthroscopy, Gastroenteroology, Gynecology, ENT (for example, DCR), Lithotripsy, Orthopedics, Discectomy and General Surgery

_ Prescription Use: __X__ **OR** Over-the-Counter Use: _____

(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060752