

K0839A



ADVANCED TECHNOLOGY LASER CO., LTD.
510(k) Summary

FEB - 2 2009

Exhibit #B 510(k) Summary

ATL Family of CO₂ Medical Laser Systems
Advanced Technology Laser Co., Ltd

(As required by 21 CFR 807.92)

1. Date Prepared: November 4, 2008

2. Sponsor Information

Advanced Technology Laser Co., Ltd.
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Shanghai, 200240, China

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3. Submission Correspondent

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Email: Diana.hong@mid-link.net

4. Proposed Device Information

Device Common or Usual Name: Carbon dioxide laser;
Device Trade or Proprietary Name: ATL Family of CO₂ Medical Laser Systems;
Model: ATL-150, ATL-250;
Classification Name: laser instrument, surgical, powered;



ADVANCED TECHNOLOGY LASER CO., LTD.
510(k) Summary

Regulation Number: 21 CFR 878.4810;

Product Code: GEX

Panel: 878 General and Plastic Surgery

5. Predicate Device

SLIM Evolution Family of CO₂ Lasers and Delivery Device Accessories
(K063001)

6. Device Description

The ATL Family of CO₂ Medical Laser Systems is a microprocessor-controlled CO₂ laser system using a sealed laser tube providing either 15 watts maximum power (ATL-150) or 25 watts maximum power (ATL-250).

The ATL Family of CO₂ Medical Laser Systems is intended to be used to deliver 10.6µm CO₂ light energy in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties.

The ATL Family of CO₂ Medical Laser Systems covers control system, user interface, power supply, laser emission and delivery system, cooling system and safety features.

7. Intended Use

The ATL Family of CO₂ Medical Laser Systems (and the delivery accessories that are used to deliver laser energy) are indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.

6. Substantial Equivalence

The ATL Family of CO₂ Medical Laser Systems share the same indications for use and safety compliance, similar design features, functional features, and therefore are substantially equivalent to the predicate device, the SLIM Evolution Family of CO₂ Lasers and Delivery Device Accessories (K063001). In addition, a review of the predicate device demonstrate that the ATL Family of CO₂ Medical Laser Systems is safe and effective as the predicate device as they share



ADVANCED TECHNOLOGY LASER CO., LTD.
510(k) Summary

equivalent wavelengths, and are used to perform the same indicated surgical procedures. Therefore the proposed device is substantially equivalent (SE) to the predicate device.

7. Testing

The ATL Family of CO₂ Medical Laser Systems is designed, tested and will be manufactured in accordance with both mandatory and voluntary standards, including:

- IEC 60825-1: 2007, Safety of laser products - Part 1: Equipment classification, requirements and user's guide.
- IEC 60601-2-22:2007, Medical Electrical Equipment – Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment.
- IEC 60601-1:1988+A1:1991+A2:1995, Medical Electrical Equipment – Part 1: General requirements for safety.
- IEC60601-1-2:2001+A1:2004, Medical Electrical Equipment – Part 1: General requirements for safety-2, Collateral Standard: Electromagnetic compatibility – Requirements and tests.

The devices also comply with European Medical Directive 93/42/EEC and the US Federal Performance Standards 21 CFR 1002.10 Requirements (21CFR 1040.10 and 21CFR 1040.11 for Class IV Laser Products), Part 820 – Quality System Regulation, and have passed ISO9001 and ISO13485 System Certification.

Non-Clinical Conclusion:

Laboratory testing was conducted to validate and verify that the proposed device, ATL Family of CO₂ Medical System met all design specifications and was substantially equivalent to the predicate device.

Clinical Conclusion: No Clinical Information is required.



FEB - 2 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Advanced Technology Laser Co., Ltd
% Underwriters Laboratories, Inc.
Mr. Morten Simon Christensen
455 E. Trimble Road
San Jose, California 95131-1230

Re: K083918

Trade/Device Name: ATL Family of CO₂ Medical 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: January 16, 2009

Received: January 23, 2009

Dear Mr. Christensen:

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

Page 2 – Mr. Morten Simon Christensen

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure



Section II Indications for Use Statement

510(k) Number: _____

Device Name: ATL Family of CO₂ Medical Laser Systems

Indications for Use:

The ATL Family of CO₂ Medical Laser Systems (and the delivery accessories that are used to deliver laser energy) are indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.

Dermatology, Plastic Surgery and General Surgery procedures including but not limited to -

- Treatment of furrows and wrinkles
- Removal of skin tags, actinic keratosis, acne scars, keloids, tattoos, telangiectasia, squamous and basal cell carcinoma, warts and uneven pigmentation.
- Treatment of cysts, abscesses, hemorrhoids and other soft tissue applications.
- Blepharoplasty
- Site preparation for hair transplants

Dental procedure including but not limited to -

- Periodontal procedures such as - gingivectomy, removal of hyperplasias, gingivoplasty (incision and excision)
- Oral Surgery procedures such as - aphous ulcer excision, frenectomy, benign/malignant lesion ablation, operculectomy and homeostasis

Podiatry procedures including but not limited to -

- Ablation, vaporization and excision of soft tissue lesions such as ingrown nail, fungal nail, paronychia, matrixectomy and verrucae vulgares.

Otorhinolaryngology (ENT) procedures including but not limited to -

- Treatment of leukoplakia of larynx, nasal obstruction, rhinophyma, verrucae vulgares, choanal atresia, LAUP and papillomatosis polyps.

Gynecology

- Treatment of condyloma acuminata, cervical intraepithelial neoplasia, leukoplakia and vulvar/vaginal intraepithelial neoplasia, cervical dysplasia.

Prescription Use X AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRL Office of Device Evaluation (ODE)

(Division Sign-Off)

Page 1 of 1

Division of General, Restorative,
and Neurological Devices

510(k) Number 1608391R