K991798 MAR - 6 2000

Attachment 17
ALTUS 510(k) Summary Statement for the [redacted] Medical Aesthetic Nd:YAG Laser Kit

I. General Information

Submitter: ALTUS [redacted] Medical, Inc.
1181 Chess Drive, Suite B
Foster City, CA 94404

Contact Person: Michael Levernier

Summary Preparation Date: May 24, 1999

II. Names

Device Names: ALTUS [redacted] Medical Aesthetic Nd:YAG Laser

Primary Classification Name: Laser Powered Surgical Instrument (and Accessories)

III. Predicate Devices

- Star Medical LightSheer Diode Laser System (K973324);
- Cynosure Apogee Long Pulse Infrared Laser (K971737); and
- Candela GentleLase GL Dermatological Laser (K981351).

IV. Product Description

ALTUS [redacted] Medical Aesthetic Nd:YAG Laser Kits are comprised of the following main components:

- a laser system console (including software and control electronics);
- a control and display panel;
- a permanently attached fiberoptic-coupled handpiece;
- a skin cooling device integrated into the handpiece;
- a finger-operated exposure switch (handswitch) integrated into the handpiece (footswitch option available)
- a remote interlock connector (disables laser when treatment room door is opened).

V. Indications for Use

ALTUS
The [redacted] Medical Aesthetic Nd:YAG Laser is intended for use in surgical and aesthetic applications requiring selective photothermolysis of target chromophores in soft tissue in general and plastic surgery and dermatology. The [redacted] Medical Aesthetic Nd:YAG Laser is indicated for the removal of unwanted hair in Fitzpatrick skin types I-V.

VI. Rationale for Substantial Equivalence

The Acme Medical Aesthetic Nd:YAG Laser shares the same general indications for use, and therefore is substantially equivalent for use in hair removal/reduction to the Star Medical/Coherent LightSheer Diode Laser System (K973324), the Cynosure Apogee Long Pulse Infrared [LPIR] Laser (K971737), and the Candela GentleLase GL Dermatological Laser (K981351).

VII. Safety and Effectiveness Information

Performance data was provided to demonstrate that the 1064 nm wavelength of the Acme Medical Aesthetic Nd:YAG Laser operates under the principles of selective photothermolysis. In addition, clinical data was provided to demonstrate that the Acme Medical Aesthetic Nd:YAG Laser is safe and effective when indicated for the removal of unwanted hair in Fitzpatrick skin types I-V in the medical specialties of general and plastic surgery and dermatology.

VIII. Conclusion

The Acme Medical Aesthetic Nd:YAG Laser was found to be substantially equivalent to the Star Medical/Coherent LightSheer Diode Laser System (K973324), the Cynosure Apogee Long Pulse Infrared [LPIR] Laser (K971737), and the Candela GentleLase GL Dermatological Laser (K981351). The Acme Medical Aesthetic Nd:YAG Laser shares similar indications for use, design features, and similar functional features as, and thus are substantially equivalent to, the currently marketed predicate devices.

Performance data and clinical study results demonstrated that the Acme Medical Aesthetic Nd:YAG Laser is safe and effective for the removal of unwanted hair in Fitzpatrick skin types I-V in the medical specialties of general and plastic surgery and dermatology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 6 2000

Mr. Michael Levernier
Director, Clinical Development
Altus Medical, Inc.
821 Cowan Road
Burlingame, California 94010

Re: K991798
Trade Name: Altus Medical Aesthetic Nd:YAG Laser
Regulatory Class: II
Product Code: GEX
Dated: January 11, 2000
Received: January 12, 2000

Dear Mr. Levernier:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2
Indications For Use Statement as Requested by FDA

510(k) Number (if Known): K991798

Device Name: ALTUS [redacted] Medical Aesthetic Nd:YAG Laser

Indications For Use:

The ALTUS [redacted] Medical Aesthetic Nd:YAG Laser is intended for use in surgical and aesthetic applications requiring selective photothermolysis of target chromophores in soft tissue in the medical specialties of general and plastic surgery and dermatology for:

- the removal of unwanted hair in Fitzpatrick skin types I-V.

(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 Devices
510(k) Number K991798

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)