K003202 JAN 1 0 2001

Attachment 18
510(k) Summary Statement for the
Family of Altus Medical CoolGlide Aesthetic Lasers

I. General Information

Submitter: Altus Medical, Inc.
821 Cowan Road
Burlingame, CA 94010

Contact Person: Michael Levernier

Summary Preparation Date: October 9, 2000

II. Names

Device Names: Family of Altus Medical CoolGlide Aesthetic Lasers

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

III. Predicate Devices

- Altus Medical Aesthetic Nd:YAG Laser (K991798 and K991234);
- VeinLase, manufactured by HGM (K981952);
- EpiLight PhotoDerm HR, manufactured by ESC Medical Systems (K991935 and K980537);
- LightSheer Pulsed Diode Array Laser System, manufactured by Star/Coherent Medical (K982940); and
- Lyra and Orion/SL/Lyra Series Laser Systems and SmartScan, manufactured by Laserscope (K990718, K990903, K941841 & K933880).

IV. Product Description

Family of Altus Medical CoolGlide Aesthetic Lasers 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 footswitch (or finger-operated exposure switch (handswitch) option integrated into the handpiece)
- a remote interlock connector (disables laser when treatment room door is opened).

V. Indications for Use

The family of Altus Medical CoolGlide Aesthetic Lasers 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. In addition, the family of Altus Medical CoolGlide Aesthetic Lasers is indicated to effect stable long-term, or permanent, hair reduction through selective targeting of melanin in hair follicles (where permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after a treatment regimen).

VI. Rationale for Substantial Equivalence

The family of Altus Medical CoolGlide Aesthetic Lasers share the same general indications for use, and therefore is substantially equivalent to the currently marketed Altus Medical Aesthetic Nd:YAG Laser (K991798 and K991234), the VeinLase, manufactured by HGM (K981952), the EpiLight PhotoDerm HR, manufactured by ESC Medical Systems (K991935 and K980537), the LightSheer Pulsed Diode Array Laser System, manufactured by Star/Coherent Medical (K982940), and the Lyra and Orion/SL/Lyra Series Laser Systems and SmartScan, manufactured by Laserscope (K990718, K990903, K941841 & K933880).

VII. Safety and Effectiveness Information

Clinical data was provided to demonstrate that the family of Altus Medical CoolGlide Aesthetic Lasers are safe and effective when indicated to effect stable long-term, or permanent, hair reduction through selective targeting of melanin in hair follicles (where permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after a treatment regimen).

VIII. Conclusion

The family of Altus Medical CoolGlide Aesthetic Lasers were found to be substantially equivalent to the currently marketed Altus Medical Aesthetic Nd:YAG Laser (K991798 and K991234), the VeinLase, manufactured by HGM (K981952), the EpiLight PhotoDerm HR, manufactured by ESC Medical Systems (K991935 and K980537), the LightSheer Pulsed Diode Array Laser System, manufactured by Star/Coherent Medical (K982940), and the Lyra and Orion/SL/Lyra Series Laser Systems and SmartScan, manufactured by Laserscope (K990718, K990903, K941841 & K933880). The family of Altus Medical CoolGlide Aesthetic Lasers share similar indications for use, design features, and similar functional features as, and thus are substantially equivalent to, the currently marketed predicate devices.

Clinical study results demonstrated that the family of Altus Medical CoolGlide Aesthetic Lasers are safe and effective when indicated to effect stable long-term, or permanent, hair reduction through selective targeting of melanin in hair follicles (where permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after a treatment regimen).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 0 2001

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

Re: K003202
Trade Name: Family of Altus Medical CoolGlide Aesthetic Lasers
Regulatory Class: II
Product Code: GEX
Dated: October 9, 2000
Received: October 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,

Miriam C. Provost for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological 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): K003202

Device Name: **Family of Altus Medical CoolGlide Aesthetic Lasers**

Indications For Use:

The family of Altus Medical CoolGlide Aesthetic Lasers are 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:

1064 nm:

- To effect stable long-term, or permanent, hair reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after a treatment regimen.
- For the removal of unwanted hair.
- For coagulation and hemostasis of vascular lesions.
- For Incision/excision of soft body tissues in dermatology.
- For soft tissue general surgery applications: skin incision; tissue dissection; excision of external tumors and lesions; complete or partial resection of internal organs, tumors, lesions; tissue ablation; vessel coagulation.

532 nm:

- For the coagulation and hemostasis of vascular and cutaneous lesions in dermatology including, but not limited to, the following general categories: vascular lesions [angiomas, hemangiomas (port wine), telangiectasia (facial or extremities telangiectasias, venous anomalies, leg veins)]; benign pigmented lesions (nevi, lentigines, chloasma, café-au-lait, tattoos (red and green ink)); verrucae; skin tags; keratoses; plaques; cutaneous lesion treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003202

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

(Optional Format 1-2-96)