

Attachment 15
510(k) Summary for the
Family of Altus Medical CoolGlide Aesthetic Lasers
With Optional Pulsed Light Hand Piece

K 022954

I. General Information

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

Contact Person: Kathy Maynor

Summary Preparation Date: November 19, 2002

II. Names

Device Names: Family of Altus Medical CoolGlide Aesthetic Lasers
With Optional Pulsed Light Hand Piece

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

III. Predicate Devices

- Prolite/Plasmalite manufactured by Medical Bio Care AB of Sweden (K013365 and K0121304 for benign pigmented lesions; other clearances for this device include K000929, K0002072, K010927, K010928, K013366, K022568, and K022569);
- Photoderm/Epilight/Quantum/Vasculight manufactured by Lumenis of Israel (K960772 for benign pigmented lesions; other clearances for this device include K963249, K974536, K991935, K994014); and
- Estelux manufactured by Palomar (K20453 and K020941 for benign pigmented lesions).

IV. Product Description

The Altus Medical CoolGlide Aesthetic Lasers with Optional Pulsed Light Hand Piece 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
- a remote interlock connector (disables laser when treatment room door is opened)
- optional pulsed light hand piece that can be removed by either the user or a qualified service person.

V. **Indications for Use**

The family of Altus Medical CoolGlide Aesthetic Lasers with Optional Pulsed Light Hand Piece are intended for use in the medical specialties of general and plastic surgery, dermatology, endoscopic/laposcopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, pulmonary/thoracic surgery and urology for surgical and aesthetic applications.

1064nm:

Dermatology:

The Altus Medical Aesthetic CoolGlide laser systems are intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins. The lasers are also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos) and plaques.

Additionally, the lasers are indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.

The CoolGlide lasers are also indicated for the treatment of wrinkles such as, but not limited to, periocular and periorbital wrinkles.

The CoolGlide lasers are also indicated for the removal of unwanted hair, for the stable long term, or permanent, hair reduction through selective targeting of melanin in hair follicles, and for the treatment for pseudofolliculitis barbae (PFB).

The lasers are also indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

The CoolGlide lasers are indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.

The intended use of the integral cooling system in the Altus handpiece is to provide cooling of the skin prior to laser treatment, for the reduction of pain during laser treatment, to allow for the use of higher fluences for laser treatments such as hair removal and vascular lesions, and to reduce the potential side effects of laser treatments.

Optional Pulsed Light Hand Piece:

For the treatment of benign pigmented lesions.

Surgical Applications:

The lasers are indicated for the incision/excision and cutting, ablation, coagulation/hemostatis of soft tissue in the performance of surgical applications in endoscopy/laprosopy, gastroenterology, general surgery, head and neck/otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, plastic surgery, pulmonary/thoracic surgery, gynecology (e.g. menorrhagia) and urology.

Indications for use (532nm):

For 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).

VI. Rationale for Substantial Equivalence

The family of Altus Medical CoolGlide Aesthetic Lasers with Optional Pulsed Light Hand Piece shares the same general indications for use, and therefore is substantially equivalent to the currently marketed

VII. Safety and Effectiveness Information

The new **indication for use** in dermatology, specifically for the treatment of benign pigmented lesions, is based upon the indications for use for predicate laser systems.

Technologically, the CoolGlide family of aesthetic lasers with optional pulsed light hand piece is substantially equivalent to the listed predicate devices. Therefore the risks and benefits for the CoolGlide laser family with optional pulsed light hand piece are comparable to the predicate devices.

We therefore believe that there are no new questions of safety or effectiveness raised by the introduction of this device.

VIII. Conclusion

The family of Altus Medical CoolGlide Aesthetic Lasers with Optional Pulsed Light Hand Piece was found to be substantially equivalent to the currently marketed The family of Altus Medical CoolGlide Aesthetic Lasers with Optional Pulsed Light Hand Piece shares similar indications for use, design features, and similar functional features as, and thus are substantially equivalent to, the currently marketed predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 18 2003

Ms. Kathy Maynor
Vice President of Regulatory
and Quality
Altus Medical, Inc.
821 Cowan Road
Burlingame, California 94010

Re: K023954

Trade/Device Name: Family of Altus Medical CoolGlide Aesthetic Lasers
with Optional Pulsed Light Hand Piece

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: February 24, 2003

Received: February 26, 2003

Dear Ms. Maynor :

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.

Page 2 - Ms. Kathy Maynor

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 (301) 594-4659. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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 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): K023954

Device Name: **Family of Altus Medical CoolGlide Aesthetic Lasers with Optional Pulsed Light Hand Piece**

Indications For Use :

This section is identical to that previously cleared on K022226 for this device family

The family of Altus Medical CoolGlide Aesthetic Lasers with Optional Pulsed Light Hand Piece are intended for use in the medical specialties of general and plastic surgery, dermatology, endoscopic/laparoscopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, pulmonary/thoracic surgery and urology for surgical and aesthetic applications.

1064nm:

Dermatology (This section is identical to that previously cleared on K022226 for this device family):

The Altus Medical Aesthetic CoolGlide laser systems are intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg veins, spider veins and poikiloderma of civatte; and treatment of benign cutaneous lesions such as warts, scars, striae and psoriasis. The lasers are also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos) and plaques.

(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
and Neurological Devices

Division Sign-off
Division of General, Restorative
And Neurological Devices

510(k) Number K023954

Prescription Use _____
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____

(Optional Format 1-2-96)

Additionally, the lasers are indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.

The CoolGlide lasers are also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.

The CoolGlide lasers are also indicated for the removal of unwanted hair, for the stable long term, or permanent, hair reduction through selective targeting of melanin in hair follicles, and for the treatment for pseudofolliculitis barbae (PFB).

The lasers are also indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

The CoolGlide lasers are indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.

The optional pulsed light hand piece is indicated for the treatment of benign pigmented lesions.

The intended use of the integral cooling system in the Altus CoolGlide laser handpiece is to provide cooling of the skin prior to laser treatment, for the reduction of pain during laser treatment, to allow for the use of higher fluences for laser treatments such as hair removal and vascular lesions, and to reduce the potential side effects of laser treatments.

Optional Pulsed Light Hand Piece (This section is new per this 510k K023954):
For the treatment of benign pigmented lesions.

(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)
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and Neurological Devices

Division Sign-off
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510(k) Number K023954

Prescription Use _____
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____

(Optional Format 1-2-96)

Surgical Applications (This section is identical to that previously cleared on K022226 for this device family):

The lasers are indicated for the incision/excision and cutting, ablation, coagulation/hemostatis of soft tissue in the performance of surgical applications in endoscopy/laprosopy, gastroenterology, general surgery, head and neck/otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, plastic surgery, pulmonary/thoracic surgery, gynecology (e.g. menorrhagia) and urology.

532nm (This section is identical to that previously cleared on K022226 for this device family):

For 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).

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