K032221

OCT 2 4 2003

SECTION 9

510(k) SUMMARY

This 510(k) summary of safety and effectiveness for the Adept 1064/755 Laser is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant: Adept Medical Concepts, Inc.

Address: 29816 Avenue De Las Banderas
Rancho Santa Margarita, CA 92688

Contact person: Mr. Jerry McFarland
President
jmcfarland@adeptmedicalconcepts.com

Telephone: 949-635-9238
949-635-9106 (fax)

Preparation Date: June 2003
(of the Summary)

Device Name: Adept 1064/755 Laser

Common Name: Surgical laser

Classification: Laser surgical instrument for use in general and plastic surgery and dermatology

Class II medical device; (21 CFR 878.4810).

Product Code: GEX
Panel: 79

Predicate devices: The Depilase Twin LASE Laser (K020412); Cynosure Apogee-TKS Laser (K992757); Candela GentleLASE GL (K994260) and GentleLASE II (K984601); Altus Family CoolGlide Aesthetic Lasers (K014040, K003202, K023954, K022226, K981798); and the Lyra Series Surgical Laser System (K990903, K003765, K003147, K010284, K010834, K020021) and the and Depilase Twin YAG Laser (K020697).

Device description: The Adept 1064/755 Laser combines a long pulse Nd:YAG laser which emits energies at 1064 nm and 532 nm and an alexandrite laser which emits energy at 755 nm.

Indications: The Adept 1064/755 Laser is indicated for coagulation and hemostasis of vascular lesions and removal and permanent reduction of unwanted hair in Fitzpatrick skin types I - VI, including suntanned skin types. Permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after a treatment regimen.

The Adept 1064/755 Laser is intended for:

755 nm wavelength

The coagulation and hemostasis of vascular lesions and the removal and permanent reduction of unwanted hair in Fitzpatrick skin types I - VI, including suntanned skin types.

1064 nm wavelength

General Surgical Applications:

For the incision, excision, coagulation, hemostasis, vaporization, and/or ablation of soft tissue in dermatology/plastic surgery, endoscopic/laparoscopic general surgery, gastroenterology, general surgery, gynecology, head and neck/otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, pulmonary surgery, thoracic surgery, and urology.

Dermatology/Plastic Surgery:

For photocoagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg and spider veins. In addition, the Adept 1064/755 Laser is 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 blue and/or black tattoos) and plaques.

The Adept 1064/755 Laser is also 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.

Cutting, incision, excision, hemostasis, coagulation, vaporization, and ablation of soft tissue in dermatology and plastic surgery.

For the treatment of facial wrinkles and wrinkles such as, but not limited to, periocular and periorbital wrinkles.

For the removal of unwanted hair, for the stable long tem, or permanent, hair reduction through selective targeting of melanin in hair follicles, and for the treatment for pseudofolliculitis barbae (PFB).

For the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

For the removal and permanent reduction of unwanted hair in Fitzpatrick skin types I - VI, including suntanned skin types.

Endoscopic/Laparoscopic Surgery:

For use in a variety of surgical procedures in several surgical specialties. These include, but are not limited to, cholecystectomy, appendectomy, vagotomy, and pyloromyomotomy where its abilities to incise, excise, coagulate, vaporize, or ablate soft tissue may be applied.

General Surgery:

For incision, excision, vaporization, ablation, and hemostasis of soft tissue general surgery applications, skin incisions, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors, lesions, tissue ablation, vessel coagulation, tonsillectomy, and hemorrhoids.

Gynecology:

For the treatment of menorrhagia by photocoagulation of the endometrial lining of the uterus, ablation of endometrial implants and/or peritoneal adhesions, soft tissue excisional procedures such as excisional conization of the cervix, intrauterine gynecologic procedures where cutting, ablation, and/or vessel coagulation may be indicated including submucous fibroids, benign endometrial polyps, and uterine septum.

Head and Neck/-Otorhinolaryngology (ENT):

For tissue incision, excision, ablation, and vessel hemostasis.

Hemostasis During Surgery:

For adjunctive coagulation and hemostasis (bleeding control) during surgery in endoscopic (e.g. laparoscopic) and open procedures.

Neurosurgery:

For hemostasis for pituitary tumor, meningioma, hemagioblastoma, AVMs. glioblastoma, astrocytoma, oligodendroglioma.

Oculoplastics:

For incision, excision, vaporization, and/or coagulation of tissues in oculoplastic procedures such as operations on the lacrimal system, operation on the eyelids, removal of biopsy or orbital tumors, enucleation on eyeball, exteneration of orbital contents.

Pulmonary Surgery:

For palliative treatment of benign and malignant pulmonary airway obstructions, including squamous cell carcinoma, adenocarcinoma, carcinoid, benign tumors, granulomas, and benign strictures.

Thoracic Surgery:

For cutting (incision/excision), coagulating, and vaporization of soft tissue. Thoracic applications, including but not limited to, isolation of vessels for endarterectomy and/or by-pass grafts, wedge resections, thoractomy, formation of pacemaker pockets; vaporization, coagulation, incision/excision, debulking, and ablation of lung tissue (thoracoscopy).

Urology:

For all applications including superficial urinary bladder tumors, invasive bladder carcinoma, urethral strictures and lesions of the external genitalia (including condyloma acuminata).

Orthopedics:

For cutting, ablation, and/or hemostasis of intra-articular tissue in orthopedic surgical and arthroscopic applications.

Performance Data: None required. The claim of substantial equivalence is based on comparisons of specifications/characteristics and intended uses of the claimed predicate.

Conclusion: Based on the information in the notification Adept Medical Concepts, Inc., believes that the Adept 1064/755 Laser is substantially equivalent to the claimed predicate(s) - see listing above for the indications for use as listed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 24 2003

Mr. Jerry McFarland
President
Adept Medical Concepts, Inc.
29816 Avenue De Las Banderas
Rancho Santa Margarita, California 92688

Re: K032221
Trade/Device Name: Adept 1064/755 Laser
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: July 17, 2003
Received: August 4, 2003

Dear Mr. McFarland:

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 (301) 594-4659. 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

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

SECTION 7

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 032221

Device Name: Adept 1064/755 Laser

Indications for Use Statement:

The Adept 1064/755 Laser is indicated for coagulation and hemostasis of vascular lesions and removal and permanent reduction of unwanted hair in Fitzpatrick skin types I - VI, including suntanned skin types. Permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after a treatment regimen.

The Adept 1064/755 Laser is intended for:

755 nm wavelength

The coagulation and hemostasis of vascular lesions and the removal and permanent reduction of unwanted hair in Fitzpatrick skin types I - VI, including suntanned skin types.

1064 nm wavelength

General Surgical Applications:

For the incision, excision, coagulation, hemostasis, vaporization, and/or ablation of soft tissue in dermatology/plastic surgery, endoscopic/laparoscopic general surgery, gastroenterology, general surgery, gynecology, head and neck/otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, pulmonary surgery, thoracic surgery, and urology.

for Mark N Melkerson

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

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

Concurrence of CDRH, Office of Device Evaluation

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

Dermatology/Plastic Surgery:

For photocoagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg and spider veins. In addition, the Adept 1064/755 Laser is 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 blue and/or black tattoos) and plaques.

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General Surgery:

For incision, excision, vaporization, ablation, and hemostasis of soft tissue general surgery applications, skin incisions, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors, lesions, tissue ablation, vessel coagulation, tonsillectomy, and hemorrhoids.

for Mark N Milhauser

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

(510(k) Number K032221

Gynecology:

For the treatment of menorrhagia by photocoagulation of the endometrial lining of the uterus, ablation of endometrial implants and/or peritoneal adhesions, soft tissue excisional procedures such as excisional conization of the cervix, intrauterine gynecologic procedures where cutting, ablation, and/or vessel coagulation may be indicated including submucous fibroids, benign endometrial polyps, and uterine septum.

Head and Neck/-Otorhinolaryngology (ENT):

For tissue incision, excision, ablation, and vessel hemostasis.

Hemostasis During Surgery:

For adjunctive coagulation and hemostasis (bleeding control) during surgery in endoscopic (e.g. laparoscopic) and open procedures.

Neurosurgery:

For hemostasis for pituitary tumor, meningioma, hemagioblastoma, AVMs. glioblastoma, astrocytoma, oligodendroglioma.

Oculoplastics:

For incision, excision, vaporization, and/or coagulation of tissues in oculoplastic procedures such as operations on the lacrimal system, operation on the eyelids, removal of biopsy or orbital tumors, enucleation on eyeball, exteneration of orbital contents.

Pulmonary Surgery:

For palliative treatment of benign and malignant pulmonary airway obstructions, including squamous cell carcinoma, adenocarcinoma, carcinoid, benign tumors, granulomas, and benign strictures.

Thoracic Surgery:

For cutting (incision/excision), coagulating, and vaporization of soft tissue. Thoracic applications, including but not limited to, isolation of vessels for endarterectomy and/or by-pass grafts, wedge resections, thoractomy, formation of pacemaker pockets; vaporization, coagulation, incision/excision, debulking, and ablation of lung tissue (thoracoscopy).

Mark N Milhern

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

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Urology:

For all applications including superficial urinary bladder tumors, invasive bladder carcinoma, urethral strictures and lesions of the external genitalia (including condyloma acuminata).

Orthopedics:

For cutting, ablation, and/or hemostasis of intra-articular tissue in orthopedic surgical and arthroscopic applications.

for Mark N Melkerson

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

510(k) Number K032221

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