MAY 0 6 2003

SECTION 10

510(k) SUMMARY K023734

This 510(k) summary of safety and effectiveness for the Aramis II Dermatological 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: Quantel Medical

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Preparation Date: February 2003 (rev.)
(of the Summary)

Device Name: Aramis II Dermatological Laser

Common Name: Er:Glass Laser

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (see: 21 CFR 878.4810).
Product Code: GEX
Panel: 79

Predicate devices: The Aramis laser (also Aramis I) - K012545 and K002649
The New Star Model 130 - K962791
The Smoothbeam Laser System - K013825
The CoolTouch and CoolTouch I - K003715

Device description: The Aramis II Dermatological Laser emits a beam of coherent light at 1540 microns which is delivered to the hand pieces, including a cooling hand piece, through a fiber optic.

Indications: The Aramis II Dermatological Laser system is intended to be used for incision/excision, ablation, and coagulation (homeostasis) of soft tissue. The Aramis II laser is also indicated for the removal of pigmented lesions; photocoagulation of dermatological vascular lesions, including photothermolysis of blood vessels (treatment of facial and leg veins), and for the treatment of periorbital and perioral wrinkles.

The Aramis Dermatological Laser is also labeled: "CAUTION: Federal law restricts the sale to or use by licensed professionals."

Performance Data: The results of pre-clinical and clinical studies were included.

A study of skin remodeling in hairless rats demonstrated that results are dose and temperature cooling dependent. Further, the thermal effects need to be controlled to reduce the risks of injury to the epidermis. Histological results showed new collagen synthesis and marked fibroblastic proliferation.

Three clinical studies in a total of 76 patients. All doses were administered in pulse trains and a cooling hand piece was used to cool the epidermis before treatment.

One clinical investigation was a dose-response study in 10 patients. The researchers reported some erythema, swelling, blistering, and crusting at higher doses. The researchers reported that lower doses should be administered to the periorbital area due to increased risk of side effects in this area.

Researchers in the other two clinical investigations reported results on 66 patients. In one study patients for followed for 6 months after the 3rd treatment; in the other they were followed for 14 months. The researchers reported there were no or only a low incidence of complications, such as pain, swelling, erythema, scabbing, or blisters. Both the periorbital and perioral areas were treated in these investigations.

Scheduled follow-ups in these two investigations, showed progressive improvement of the skin texture and the wrinkles. There were no unwanted side effects except for a brief erythema linked to the cooling. In one study biopsies were taken 6 months after the first treatment and showed significant increases in collagen.

The investigators suggested that the dose be administered as a train of pulses, that the skin should be cooled to 5°C, and that the fluence be controlled to avoid the critical temperature which leads to cell destruction.

The investigators also suggested that patients be advised that the remodeling progresses slowly over several months and that they should not be disappointed by a lack of immediate effects.

CONCLUSION: Based on the information in this notification Quantel Medical concludes that the Aramis II, when intended to be used for incision/excision, ablation, and coagulation (homeostasis) of soft tissue for the removal of pigmented lesions; photocoagulation of dermatological vascular lesions, including photothermolysis of blood vessels (treatment of facial and leg veins) is substantially equivalent to cited legally marketed predicates.

Quantel further concludes that the Aramis II intended the treatment of periorbital and perioral wrinkles skin remodeling, is safe and effective for these applications based on clinical studies and the ARAMIS II is substantially equivalent to cited legally marketed products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 6 2003

Quantel Medical
c/o Mr. Roger Barnes
342 Sunset Bay Road
Hot Springs, Arkansas 71913

Re: K023734
Trade/Device Name: ARAMIS II Dermatological 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: February 10, 2003
Received: February 11, 2003

Dear Mr. Barnes:

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. 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,

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

SECTION 7

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K023734

Device Name: Aramis II Dermatological Laser

Indications for Use Statement:

The Aramis II Dermatological Laser system is intended to be used for incision/excision, ablation, and coagulation (homeostasis) of soft tissue. The Aramis II laser is also indicated for the removal of pigmented lesions; photocoagulation of dermatological vascular lesions, including photothermolysis of blood vessels (treatment of facial and leg veins), and for the treatment of periorbital and perioral wrinkles.

The Aramis II Dermatological Laser is also labeled: CAUTION: Federal law restricts the sale to or use by licensed professionals.

Miriam C. Provost

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

rev. 2/2003

510(k) Number K023734

(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)