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ATTACHMENT #3

NOV 2 0 2003

SECTION 9

510(k) SUMMARY

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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+33 (0)473 745 745
+33 (0)473 745 700 (Fax)

Contact Person: Mr. Jean Abascal

(+33) 169 29 17 25
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Preparation Date: July 2003
(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 Smoothbeam Laser System - K014128

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

Indications: The ARAMIS II Dermatological Laser system, in addition to previously cleared indications, is intended for the treatment of back acne.

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Performance Data: None required; the ARAMIS II claims substantial equivalence to the Candela Smoothbeam based on comparisons of specifications/characteristics and indications for use

CONCLUSION: Based on the information in this notification Quantel Medical concludes that the ARAMIS II, indicated for the treatment of back acne, is substantially equivalent to the Candela Smoothbeam.

rev. August 15, 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2003

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

Re: K032260
Trade/Device Name: Aramis II Dermatological Laser – New Indication
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: October 22, 2003
Received: October 28, 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. 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,

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): K032260

Device Name: Aramis II Dermatological Laser - New indication

Indications for Use Statement:

The Aramis II Dermatological Laser system is intended for the treatment of back acne.

Miriam C. Provost

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

510(k) Number K032260

(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)