APR 2 7 2005

510(k) Summary of Safety and Effectiveness

K041554

This 510(k) Summary of Safety and Effectiveness for the AesThera AIP ™ Intense Pulsed Light System is submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organization and content of a 510(k) summary.

Applicant:	AesThera Corporation 6111 Southfront Road Suite E Livermore, CA 94550 Bob Anderson Chief Financial Officer
Contact Person:	C. Robert Payne, Jr., P.E. Regulatory Affairs Consultant CRP Enterprises P.O. Box 2608 Morgan Hill, CA 95038 Telephone: (408) 782-3024 Fax: (408) 779-5284 e-mail: myrvhome@ix.netcom.com
Preparation Date:	6 June 2004
Device Trade Name:	AIP™ Intense Pulsed Light System
Common Name:	Pulsed Flash Lamp
Classification Name:	Surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878-4810)
Product Code:	GEX

Predicate Devices:

- SkinStation™, SPR™, ClearTouch™ , SpaTouch Pro (XtremeClear ™), SpaTouch ™ (Radiancy (Israel) Ltd.)
  (K032205, K033181, K030897, K020856, K992482)

- StarLux™, MediLux™, EsteLux™ (Palomar Medical Technologies, Inc.)
  (K033549, K020941, K020453, K010618, K003886)

Device Description:

The AesThera AIP Intense Pulsed Light System is a 400–1200 nm intense pulsed light delivery system, powered by Photo-Pneumatic™ technology. It is a portable tabletop system with a hand piece connected by an umbilical to the main console. The hand piece incorporates an intelligent tip that is replaced with every patient treatment. A "sealed" intelligent tip is used to transmit light to the patient's skin. Light is emitted only through the tip and is always sealed with the patient's surrounding tissue during intense pulsed light emission. All emitted light is contained within the tip during treatment. The hand piece of the AIP Intense Pulsed Light System is uniquely designed to promote increased ergonomics with all user interface and controls located on the hand piece.

Intended Use of the Device:

The AIP Intense Pulsed Light System is an intense pulsed light device intended for the following: the treatment of benign vascular and pigmented lesions, and permanent hair reduction.

The AIP Intense Pulsed Light System is intended for use on all skin types (Fitzpatrick skin types I-VI).

Substantial Equivalence to Predicate Devices:

The AIP Intense Pulsed Light System, which is intended for the following; the treatment of benign vascular and pigmented lesions, and permanent hair reduction, is substantially equivalent in design and materials to the listed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 2005

AesThera Corporation
C/o C. Robert Payne, Jr., P.E.
RA/ QA Consultant
CRP Enterprises
P.O. Box 2608
Morgan Hill, California 95038

Re: K041554
Trade/Device Name: AIP™ Intense Pulsed Light System
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: March 16, 2005
Received: March 21, 2005

Dear Mr. Payne:

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 (240) 276-0115 . 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/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: New submission K041554

Device Name: AIP ™ Intense Pulsed Light System

Indications for Use:

The AIP Intense Pulsed Light System is an intense pulsed light device intended for the following: the treatment of benign vascular and pigmented lesions, and permanent hair reduction.

The AIP Intense Pulsed Light System is intended for use on all skin types (Fitzpatrick skin types I-VI).

Prescription Use _X_ OR Over-the-Counter Use ___
(per 21 CFR 878-4810)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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[illegible]
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