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Section 1– 510(k) Summary or 510(k) Statement

I. General Information

JUL - 8 2010

Submitter: Theravant Corporation
201 Lindberg Ave
Livermore, CA 94551
USA

Contact Person: Marcy Moore
Regulatory Consultant for
Theravant Corporation
131 Kelekent Lane
Cary, NC 27518
919-363-2432 ph
919-363-0085 fax
marcymoore@nc.rr.com

Summary Preparation Date: May 14, 2010

II. Names

Trade Name: TheraClear System

Classification: Class II

21 CFR 878.4810

Product Code: ONF

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

III. Predicate Device(s)

- Aesthera Isolaz System (K083730);

IV. Product Description

The Theravant System is comprised of the following main components:

- Main console
- Treatment Handpiece(s)

The Theravant System is a portable tabletop system used to deliver intense pulsed light to the patient treatment site via a delivery handpiece utilizing vacuum technology. Intense pulsed light is emitted through the tip only when the tip is sealed against the selected patient treatment site. All emitted light is contained within the tip during treatment.

V. Indications for Use

The Theravant TheraClear System is intended for:

- The treatment of benign vascular and pigmented lesions;
- Permanent hair reduction;
- The treatment of mild to moderate acne, including pustular acne, comedonal acne, and mild to moderate inflammatory acne (acne vulgaris).

The TheraClear System is intended for use on all skin types (Fitzpatrick types I-VI).

VI. Rationale for Substantial Equivalence

The TheraClear System shares the identical indications for use as the named predicate(s), and same or similar device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate devices.

VII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics demonstrates that the TheraClear System is substantially equivalent to the predicate devices.

VIII. Conclusion

The Theravant System was found to be substantially equivalent to the predicate devices.

The Theravant System shares the identical indications for use as the named predicate(s), and same or similar device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Theravant Corporation
% Ms. Marcy Moore
Regulatory Consultant
131 Kelekent Lane
Cary, North Carolina 27518

JUL - 8 2010

Re: K101415
Trade/Device Name: TheraClear System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: ONF
Dated: May 19, 2010
Received: May 20, 2010

Dear Ms. Moore:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

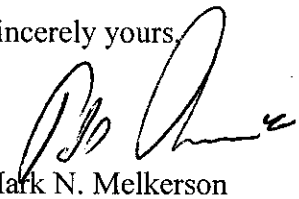
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K101415

Device Name: TheraClear

Indications for Use:

The Theravant TheraClear System is intended for the treatment of benign vascular and pigmented lesions; permanent hair reduction; and the treatment of mild to moderate acne, including pustular acne, comedonal acne, and mild to moderate inflammatory acne (acne vulgaris), in all skin types (Fitzpatrick I-VI).

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K101415