K090831

SECTION 15 - 510(k) SUMMARY

MAY 29 2009

The 510(k) Summary is contained on the following pages.

510(k) Summary

For

TanThera-T35 UVA1 Light Emitting Diode Tanning Chamber

Date Prepared: March 19, 2009

Section 15.1 – Sponsor Information

Contact Person:
Peter D. Fiset, CEO
Phone: 518.281.7383
Email: PeterFiset@Opthera.com

Christopher W. Macomber, COO
Phone: 518.265.2882
Email: ChrisMacomber@Opthera.com

Opthera, Inc.
5 Upper Loudon Road
Loudonville, NY 12211
USA
Fax: 518.436.0485

Section 15.2 – Outside Regulatory Counsel

Foley & Lardner LLP
3000 K St., NW
Suite 500
Washington, DC 20007

Contact Person: Nathan A. Beaver
(202) 295-4039 (telephone)
(202) 672-5399(facsimile)
nbeaver@foley.com (email)

K090831

Section 15.3 – Device Name

♦Proprietary Name: TanThera-T35

♦Common/Usual Name: UVA1 Light Emitting Diode Tanning Chamber

♦Classification Names and Numbers: Ultraviolet lamp for tanning, General Hospital, LEJ.

Section 15.3 – Device Description and Intended Use

Indications for Use: Intended to provide ultraviolet light to tan the skin.

The TanThera-T35 ("T35") is a tanning chamber employing UVA1 (340 nm – 400 nm) light-emitting diode ("LED") technology as the ultraviolet light source in order to provide a tanning response to human skin. It is designed in a clam-shell format with an upper ("canopy") and lower ("bench") radiant surface in order to provide a two-sided tan with a person in supine position on an acrylic platform.

The principle parts of the T35 include multiple T35 LED Modules, forty-four (44) copper tube heat sink with a linear array of thirty-eight (38) T35 LED Modules each, a T-Max ® Timing System, a temperature control system, and a chilled-water liquid cooling system. The copper tube arrays with temperature equalizing internal counter-current flow dams, are arranged with twenty-six (26) tube arrays on the canopy and eighteen (18) tube arrays on the bench. The tube arrays are mounted behind a diffuse reflector that has cutouts for each of the T35 LED Modules. There is an acrylic shield between the tanner and the arrays to prevent tampering and contact with T35 LED Modules as well as to provide a minimum distance from the emitters to the tanner. The liquid cooling system has temperature and flow controls that sense and control water flow to maintain the LED modules at an operating temperature range. The bed is designed to terminate operation if the operating parameters of the T35 LED Modules are not met. Should the T35 LED Module temperature increase due to low coolant flow or high coolant inlet temperatures then the session terminates to prevent overheating and possible early burnout of the LED modules. A failure of the cooling system decreases LED lifetime but does not pose a significant risk to the tanner.

The T35-LED Module is comprised of Nichia Chip-Type LEDs (Model NCSU033A), a power connector, a fuse, and a 700 mA nominal current regulator. The T35-LED Module (Model 3N33X1) is clearly marked with a recommended lifetime of 10,000 hours. The T35 is powered by low-voltage DC power (13 ± 0.5 VDC, 12 ± 0.1 VDC, - 12 ± 0.1 VDC) and low-voltage DC-DC converters located in the bench of the tanning chamber with redundant fans for cooling. T35 LED Modules are replaceable by TanThera certified technicians only.

The T35 has a nominal peak wavelength output of 365nm and a maximum tanning session of 35 minutes. The total tanning chamber output less than 1250 W of UVA1 light. An industry de-facto standard T-Max® timer regulates the session. The T35

incorporates a manual session termination switch that allows a tanner to discontinue a session at any time.

Tanners are instructed and required to wear FDA-cleared eye protection and to follow the tanning instructions as provided in the User Manual.

Section 15.4 – Predicate Device

♦Suntana SunSystem SunBed and SunBrella, FDA 510(k) Reference Number K800744, Output Range: UVA-only
♦Currently marketed UVA1 bulb shown to effectively tan: Philips TL10
♦Substantial Equivalence Comparison:

The TanThera-T35 is substantially equivalent to currently marketed sunlamp products. The predicate scenario established to demonstrate substantial equivalence of the T35 to current sunlamp products utilized the FDA 510(k) approved Suntana SunSystem, SunBed and SunBrella for structural and operational equivalence, and the Philips TL10 UVA1 lamp for spectral irradiance equivalence for effective tanning.

The T35 represents a change in technology from mercury vapor based lamps to light-emitting diodes. With the exception of the change of emitter technology, no significant structural or performance changes are present in the T35 when compared to the Suntana SunSystem, and the Philips TL10 UVA1 lamp, nor are there significant changes when compared to other currently marketed sunlamp products. The spectral output, mode of operation, and general operating principles are similar to or the same as the listed predicates and currently available sunlamp products. Although there are some differences in the production of UV light compared to other sunlamp products, the differences do not raise any questions in regard to safety or efficacy. Therefore, the TanThera-T35 LED tanning chamber, when used in accordance with the user manual, is structurally substantially equivalent to the Suntana SunSystem and SunBrella tanning bed, and spectrally substantially equivalent to the Philips TL10 UVA1 bulb.

Section 15.5 – Performance Characteristic Summary

The TanThera-T35 design references applicable parts of the FDA document "Sunlamp products and ultraviolet lamps intended for use in sunlamp products" (21 CFR 1040.20) April 1, 2008, which outlines performance standards for sunlamps and sunlamp products, and the FDA document "GUIDE FOR PREPARING PRODUCT REPORTS ON SUNLAMPS AND SUNLAMP PRODUCTS (21 CFR 1002)", September 1995 (Address corrections Aug. 2008).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 29 2009

TanThera, Inc.
% Foley & Lardner LLP
Mr. Nathan A Beaver
Washington Harbour
3000 K Street, Northwest, Suite 500
Washington, District of Columbia 20007

Re: K090831
Trade/Device Name: TanThera – T35
Regulation Number: 21 CFR 878.4635
Regulation Name: Ultraviolet lamp for tanning
Regulatory Class: I
Product Code: LEJ
Dated: March 26, 2009
Received: March 26, 2009

Dear Mr. Beaver:

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 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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at

(240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (If known): K090831

Device Name: TanThera - T35

Indications For Use: Intended to provide ultraviolet light to tan the skin.

Prescription Use X (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) for MKM

Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K090831