DEC 2 0 2013

ATTACHMENT 2

510(k) SUMMARY

510(k) Owner:	Sunetics International Marketing Group LLC 892 Steger Towne Rd Suite # 44 Rockwall, TX 75032 Contact: John Carullo Phone: 214-683-0724	
Date Summary Prepared:	August 9, 2013	
Device:	Trade Name:	Sunetics Clinical Laser "G" or "W2326"
	Common/Classification Name:	Light Therapy Hair System Product Code OAP; NHN 21 C.F.R. § 890.5500 (Infrared lamp)
	Classification:	Class II
Predicate Devices:	MEP-90 Hair Growth Stimulation System - Midwest RF LLC - K091496 i grow II Hair Growth System - Apira Science Inc - K122248 Theradome LH80 PRO Laser Helmet - Theradome Inc - K122950 Theradome Laser Helmet LH80 PRO - Theradome Inc - K113097	
Device Description:	The Sunetics Clinical Laser (model "G" & model "W2326") is a stationary, non-invasive, low-level laser device intended to treat Androgenetic Alopecia (Hair Loss) and to promote hair growth in both Males and Females. The Sunetics Clinical Laser device provides distributed red laser light dispersing from an "Open Panel" Hood utilizing laser modules with a 650 nm wavelength, <5 mW output power, producing a continuous wave "CW" output beam. The "Open Panel" Hood is designed to maximize the delivery of the coherent laser light to effectively cover the entire scalp of the user during treatment.	

Intended Use:	The Sunetics Clinical Laser (model "G" & model "W2326") is indicated to treat Androgenetic Alopecia (Hair Loss) and to promote hair growth in Males who have Norwood Hamilton Classifications of IIa to V and Fitzpatrick Skin Types I to IV and also in Females who have Ludwig (Savin) I-4, II-1, II-2, or frontal patterns of hair loss & Fitzpatrick Skin Types I to IV.
Technological Characteristics:	The Sunetics Clinical Laser (model "G" & model "W2326") is a stationary device that produces red laser energy dispersed from an "Open Panel" Hood array as it rests slightly above a patient's head and creates a laser field that covers the patients entire scalp area. The device produces timed treatments of equally distributed laser energy to the full scalp area. The medically prescribed treatment received from the laser energy promotes hair growth in Males and Females and treats Androgenetic Alopecia (Hair Loss) by the therapeutic modality of bio-stimulation.
Biocompatibility Data:	Not applicable.
Performance Data:	The evaluation of the perfomance data presented confirms that the Sunetics Clinical Laser (model "G" & model "W2326") has the same or similar laser wavelength, output power, output beam, energy type, laser field, treament area and energy delivery as the FDA Cleared predicate devices. Testing to IEC 60601-1 and 60601-1-2 confirm the devices adherence to LVD electrical and EMC safetly requirements. Testing to IEC 60825-1 certifies the laser system to classifaction 3R, which is the same as the predicate devices. Performance Testing is conducted to confirm compliance to design specifications; all functions were verified to operate as designed. The Sunetics Clinical Laser met all acceptance criteria in the performance testing.
Conclusions:	The Sunetics Clinical Laser (model "G" & model "W2326") is as safe and effective as the FDA Cleared predicate devices and is thefore Substantial Equivalent to the FDA Cleared predicate devices with respect to intended use, technological characteristics and safety characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Sunetics International Marketing Group LLC
Mr. John Carullo
Managing Member
892 Steger Towne Road, Suite 44
Rockwall, Texas 75032

December 20, 2013

Re: K132646
Trade/Device Name: Sunetics Clinical Laser "G" or "W2326"
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: OAP, NHN
Dated: November 21, 2013
Received: November 25, 2013

Dear Mr. Carullo:

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 contact 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. 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,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
For Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number ___K132646_____
(if known):

Device Name: Sunetics Clinical Laser ..... models: "G" & "W2326"

Indications for Use: The Sunetics Clinical Laser is indicated to treat Androgenetic Alpopecia (Hair Loss) and to promote hair growth in Males who have Norwood Hamilton Classifications of IIa to V and Fitzpatrick Skin Types I to IV.

The Sunetics Clinical Laser is indicated to treat Androgenetic Alpopecia (Hair Loss) and to promote hair growth in Females who have Ludwig (Savin) I-4, II-1, II-2, or frontal patterns of hair loss and Fitzpatrick Skin Types I to IV.

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

Neil R Ogden -S
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(Division Sign-Off) for BSA

Division of Surgical Devices

510(k) Number K132646