

510(k) Summary

(as required per 21CFR; §807.92)

FEB 23 2010

MEP-90 Hair Growth Stimulation System

I. Applicant Midwest RF LLC
1050 Walnut Ridge Drive
Hartland, WI 53029 USA

Phone: (262) 867-8254
Fax: (262) 867-8554

II. Contact Name Helmut Keidl, President
helmut@midwestcomposite.com

III. Device Name

Proprietary Name MEP-90 Hair Growth Stimulation System
Common/Usual Name(s) Light Therapy Hair System
Classification Name Infrared Lamp per 21CFR 890.5500
Product Code(s) OAP; NHN

IV. Predicate Devices

<u>510(k) Number</u>	<u>Device</u>	<u>Manufacturer</u>
K060305	Hairmax Lasercomb	Lexington International LLC
K032816	Quantum Light Therapy System	Stargate International

VI. Indications For Use

The MEP-90 is a non-heating lamp as described under the provisions of 21 CFR §890.5500 and is indicated for:

Medically prescribed use for the treatment of androgenic alopecia in females;

The treatment of androgenic alopecia in females by promoting hair growth of females with androgenetic alopecia who have Ludwig and Savin Hair Loss Scale classifications of I to II and who have been determined to have a Fitzpatrick Skin Typing of I to IV.

VII. Technological Characteristics

The MEP-90 is a stationary low-level laser device that promotes hair growth and provides treatment for androgenic (androgenetic) alopecia in females. The device provides automated and timed equal distribution of laser light to 100% of the scalp.

The MEP-90 operation is controlled by an operating system that affords the user maximum flexibility for individual treatments. The device applies a measured very high tolerance ($\leq +.76\%$) wavelength (λ) to the scalp stimulating hair growth by the proven concept of biostimulation.

VII. Performance Data And Clinical Efficacy

A multi-phased experimental study was performed with Institutional Review Board (IRB) pre-approval and oversight, in accordance with all applicable references of the Food and Drug Cosmetic Act and Title 21; Code of Federal Regulations.

Androgenic alopecia in women is a chronic medical condition requiring diagnosis, treatment, and monitoring by a licensed medical physician. The condition in women demonstrates both physical and emotional symptoms, which requires addressing by a licensed medical professional.

For the MEP-90 efficacy determination, each subject received a total of 36 each, 20-minute treatments with the MEP-90, over a period of 18 weeks. Results were reviewed at the 10-Week (20 treatment) and 18-Week (36 treatment) levels.

After 20 treatments (10-Weeks), 92% of the subjects demonstrated an increased hair count of $\geq 10\%$ with 57% demonstrating an increase of $\geq 30\%$. 98% of the subjects indicated a medically significant stabilization of their rate of hair loss.

After the 36th treatment, 97% of the subject population demonstrated an increased hair count of $\geq 20\%$. A total of 89% of all subjects demonstrated an increased hair count of $\geq 30\%$, with 57% demonstrating an increased hair count of $\geq 50\%$.

87% of the subjects indicated the treatments have helped their condition, with 60% reporting their loss rate has further slowed down from the 10-week period, and 65% reported their visible area of the alopecia (bald spot) had gotten smaller.

100% of the linear trend plotting for all subjects of their Initial, 10-Week, and 18-Week hair counts demonstrated a historical rate of increased hair growth.

No subject experienced any adverse event and/or effect from the treatments.

VI. Substantial Equivalency

The MEP-90 is substantially equivalent to other pulsed therapeutic light therapy systems currently in commercial distribution. The MEP-90 has the same intended use to the predicate device approved for commercial distribution under 510(k) number K060305 and technological and safety characteristics to the predicate device approved for commercial distribution under 510(k) number K032816.

It exceeds the clinically accepted therapeutic results standards of FDA 510(k) K060305 previously approved light therapy system into a system which provides a more controlled application and larger treatment coverage area at no increased risk to the patient.

The technological equivalence to the predicate devices is substantiated by the wavelength and power output generated by the MEP-90. The MEP-90 provides expanded treatment benefits and regimens for clinical presentations already approved by the Food and Drug Administration for the predicate device.

The MEP-90 is as safe and effective as a combination of the predicate devices listed and numerous others. It has the same intended use of affecting hair growth as the hair growth predicate device (K060305). In addition, the MEP-90 has the same general indications, i.e., treating androgenic alopecia, and the same specific indication of promoting hair growth as the predicate device.

The MEP-90 also has many of the same or similar technological characteristics as a combination of its predicate devices. These include multiple lasers and visible laser wavelength.

The technological differences between the MEP-90 and its predicate devices, specifically the use of red laser to treat androgenic alopecia in females, does not raise new questions of safety or effectiveness for several reasons:

First, the safety and effectiveness profile of the type, wavelength, and power output of this type of laser is well established and previously cleared by the FDA.

Second, FDA's clearance of the predicate device with a much wider wavelength tolerances than the MEP-90's, confirms the favorable risk benefit ratio of visible lasers.

Third, the clinical data acquired confirms both the safety and effectiveness of the MEP-90 for prescription use in promoting hair growth in the intended patient population, despite the difference in technological characteristics between the MEP-90 and K060305. The data demonstrates clear statistical significance of the treatment results obtained and provide mathematical certainty that the results attained did not occur by chance.

These facts exceed FDA's substantial equivalence requirements with respect to the intended use, clinical efficacy, and technological characteristics of the MEP-90.

While there are some technological differences between the MEP-90 and its predicate devices, Midwest conducted an Institutional Review Board approved and monitored clinical study, with the MEP-90, to show that the device functions as intended for its proposed indication for use without any serious side effects or risks.

The clinical and effectiveness data demonstrates that the MEP-90 is effective in promoting hair growth, does not present any safety issues, is classified by the FDA as a non-significant risk (NSR) device, therefore the FDA should approve the medical device by approval of the 510(k).



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

FEB 23 2010

Midwest RF, LLC
% Mr. Helmut Keidl
President
1050 Walnut Ridge Drive
Hartland, Wisconsin 53029

Re: K091496

Trade/Device Name: MEP-90 Hair Growth Stimulation System
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: OAP
Dated: January 15, 2010
Received: January 20, 2010

Dear Mr. Keidl:

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.

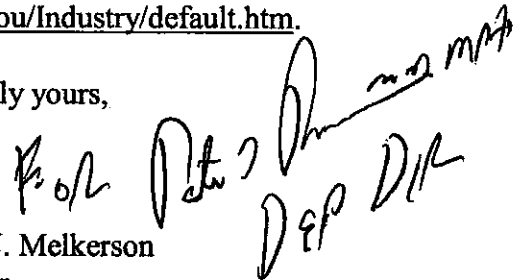
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', with some additional scribbles and initials to the right.

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

510(k) Number: K091496

Device Name: MEP-90 Hair Growth Stimulation System


Indications For Use: The MEP-90 is a non-heating lamp as described under the provisions of 21 CFR §890.5500 and is indicated for:

The treatment of androgenic alopecia in females by promoting hair growth of females with androgenetic alopecia who have Ludwig and Savin Hair Loss Scale classifications of I to II and who have been determined to have a Fitzpatrick Skin Typing of I to IV.

Prescription Use: **AND/OR** **Over The Counter Use:**
(Part 21 CFR 801 Subpart D)

(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 12091496