



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

Apr 19 2011

Lexington International, LLC
% Olsson Frank Weeda
Casper E. Uldriks, Esq.
1400 Sixteenth Street, Northwest
Washington, District of Columbia 20036

Re: K103368

Trade/Device Name: HairMax LaserComb Advanced 7, HairMax LaserComb Lux 9 and
HairMax LaserComb Professional 12

Regulation Number: 21 CFR 890.5500

Regulation Name: Infrared lamp

Regulatory Class: Class II

Product Code: OAP

Dated: January 26, 2011

Received: March 15, 2011

Dear Mr. Uldriks:

This letter corrects our substantially equivalent letter of April 6, 2011.

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 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number: To be assigned

Device Name: HairMax LaserComb Advanced 7, HairMax LaserComb Lux 9 and
HairMax LaserComb Professional 12

Indications for Use:

The HairMax LaserComb Advanced 7 is indicated to treat androgenetic alopecia and promote hair growth in males who have Norwood Hamilton Classifications of IIa to V patterns of hair loss and Fitzpatrick Skin Types I to IV.

The HairMax LaserComb Lux 9 is indicated to treat androgenetic alopecia and promote hair growth in males who have Norwood Hamilton Classifications of IIa to V patterns of hair loss and Fitzpatrick Skin Types I to IV.

The HairMax LaserComb Professional 12 is indicated to treat androgenetic alopecia and promote hair growth in males who have Norwood Hamilton Classifications of IIa to V patterns of hair loss and Fitzpatrick Skin Types I to IV.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 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. Dede for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103368