

K08320e
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510(k) Summary

Larada Sciences, Inc. LouseBuster™

MAR 10 2009

1 Preparation Date 28 October 2008

Submitted By

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Contact Person/ Prepared By

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2 Device Identification

Trade Name LouseBuster™
Common Name Louse Eradication System
Classification Name Lice Removal Kit §880.5960

3 Predicate Device(s)

Robi Comb (cleared under K930859)

4 Device Description

The LouseBuster (LB) is a portable, electrically powered, reusable, prescription-use device that can be used to direct controlled, heated airflow to kill Lice on the hair and scalp of patients with head lice infestations.

The device consists of an applicator, a flexible delivery hose, and a base unit comprising heating and air movement elements with associated safety monitoring and temperature control circuitry. The mechanical and electrical components of the device are protected in a molded, non-metallic housing. A detachable delivery hose provides a pathway for channeling the flowing, heated air created in the base unit to the single-use, disposable applicator. The single-use applicator is attached to the hose by the user before initiating LB treatment. During treatments, the applicator is

manually positioned by the user to systematically direct heated air to kill or remove lice present in the scalp and hair roots of an infested individual.

5 Intended Use

The LouseBuster™ is intended for use to kill or remove lice and lice eggs in the head hair of adults and children 4 years of age and older.

6 Comparisons and Conformance with Standards

The device complies with the requirements of UL60601-1 and IEC60601-1-2. Results of additional design verification studies demonstrated that the device met pre-defined acceptance criteria for electrical and mechanical performance. Biological safety risks were found to be acceptable in accordance with ISO 10993-1 and FDA Memo G95-1.

A clinical trial was conducted that demonstrated that the safety and efficacy of the LouseBuster device was equivalent to that of the predicate device. Additionally, clinical study results demonstrated that individuals successfully completing Larada's Training Program deliver safe and effective LouseBuster treatments to individuals infested with head lice.

7 Conclusion

The LouseBuster is substantially equivalent to the predicate Robi Comb and is safe and effective for its intended use.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-0609
Silver Spring, MD 20993-0002

Larada Sciences, Incorporated
C/O Phil Triolo, PhD, RAC
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NOV 22 2009

Re: K083206
Trade/Device Name: Larada Sciences LouseBuster™ Lice Eradication System
Regulation Number: 21 CFR 880.5960
Regulation Name: Lice Removal Kit
Regulatory Class: I
Product Code: LJL
Dated: February 27, 2009
Received: March 2, 2009

Dear Dr. Triolo:

This letter corrects our substantially equivalent letter of March 10, 2009.

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 (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.

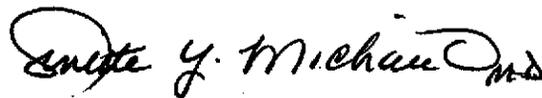
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



Ginette Y. Michaud, M.D.

Acting Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

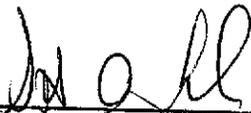
Device Name: **Larada Sciences LouseBuster™ Lice Eradication System**

Indications For Use: **The LouseBuster™ is intended for use to kill or remove lice and lice eggs in the head hair of adults and children 4 years of age and older.**

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)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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