K082087

SEP 1 1 2008

510(k) SUMMARY

Bio-Lipid EyeFeel Ophthalmic Warmer

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Bio-Lipid, Inc.
7000 SW 97th Avenue
Suite 212
Miami, FL 33173
Phone: 305-412-4430
Facsimile: 305-412-4429

Contact Person: Dr. Scheffer Tseng

Date Prepared: July 15, 2008

Name of Device and Name/Address of Sponsor

EyeFeel Ophthalmic Warmer

Bio-Lipid, Inc.
7000 SW 97th Avenue
Suite 212
Miami, FL 33173

Common or Usual Name

Hot or Cold Disposable Pack

Classification Name

21 C.F.R. § 890.5710 (Hot or Cold Disposable Pack)

Predicate Devices

EyeFeel Ophthalmic Warmer
Bio-Lipid, Inc.
K021834

Intended Use / Indications for Use

The EyeFeel ophthalmic warmer is a hot disposable pack for the application of localized heat therapy in cases of chronic inflammatory and cystic conditions of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye or lipid deficiency dry eye, and chalazia.

The EyeFeel Ophthalmic Warmer also may relieve accommodative fatigue and may help recover baseline visual acuity levels after prolonged work on visual display terminals.

Technological Characteristics

The EyeFeel Warmer consists of a front layer, two oval shaped sacks that hold the iron powder mixture, and a back inner layer that is placed on the face. The iron powder mixture consists of iron powder, sodium chloride, filtrated water, powdered activated carbon, granular activated carbon, sodium polyacrylate powder, and exfoliated vermiculite.

Performance Data

A small clinical study was conducted to assess the effect of the EyeFeel Warmer on periocular accommodation fatigue and visual acuity after prolonged work on visual display terminals. The results of the study support the expanded indications of the EyeFeel Warmer.

Substantial Equivalence

The EyeFeel Warmer that is subject of this premarket notification is identical to the predicate EyeFeel Warmer that was cleared under K021834 with the exception of the indications for use. Both the proposed and predicate EyeFeel Warmer devices have the same intended use and same technological characteristics. Therefore the proposed EyeFeel Warmer is substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 1 2008

Bio-Lipid, Inc
c/o Pamela Furman
King & Spalding, LLP
1700 Pennsylvania Ave., NW
Washington, DC 20006

Re: K082087
Trade/Device Name: EyeFeel Ophthalmic Warmer
Regulation Number: 21 CFR 890.5710
Regulation Name: Hot or cold disposable pack
Regulatory Class: Class I
Product Code: IMD
Dated: July 23, 2008
Received: July 23, 2008

Dear Ms. Furman:

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,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082087

Device Name: EyeFeel Ophthalmic Warmer

Indications for Use:

The EyeFeel ophthalmic warmer is a hot disposable pack for the application of localized heat therapy in cases of chronic inflammatory and cystic conditions of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye or lipid deficiency dry eye, and chalazia.

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[IDENTIFY WHETHER THE DEVICE IS INTENDED FOR PRESCRIPTION USE AND/OR OVER-THE-COUNTER USE.]

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mia-Chuen Shih

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K082087