K091915

OCT 2 7 2009

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510(k) Summary (21 CFR 807.92)

Date Summary Prepared: June 25th, 2009

Lenstec Inc.
510(k) Premarket Notification Submission
Lenstec Fluid Isolation Device (FID)
510(k) Premarket Notification Summary

Trade/Device Name: Fluid Isolation Device (FID)
Lenstec Inc Establishment Registration Number: 1063199
Type of 510(k) Submission: Traditional
Reason for Submission: New Device
Regulation Number: 21 CFR 886. 4670
Regulation Name: Phacofragmentation system
Regulatory Class: Class II
Product Code: HQC

Confidentiality:
Lenstec requests that the Agency treat the contents of this submission as confidential and proprietary to Lenstec Inc

Labeling:
Federal (United States) Law restricts this device to sale by or on the order of a physician

1. Applicant Information:
   a. Name: Lenstec Inc.
   b. Address: 1765 Commerce Ave N
      St. Petersburg, FL 33716
      Telephone Number: (727) 571-2272
      Fax Number: (727) 571-1792
   c. Contact Person: Jimmy Chacko, Vice President, Regulatory Affairs (Email: JChacko@Lenstec.com)

2. Name of Device
   a. Trade Name: Fluid Isolation Device
   b. Common Name: FID
   c. Classification Name: Phacofragmentation system (HQC, 886.4670)

3. Substantially Equivalent legally-marketed devices:

a. Milvella Perfect Capsule (K030957)

4. Device Description
The Fluid Isolation Device (FID) is a medical device which is intended to hold and seal the lens capsule, to allow irrigation of the capsular bag in an aphakic patient, in order to remove residual cortex and/or epithelial cells. The system consists of the following components:
   - Vacuum ring suction cup connected to lure lock with silicone tubing
   - 20 mL Vaclok Syringe

   Following cataract extraction, the device's vacuum ring suction cup is placed onto the posterior surface of the anterior capsule, and a seal is created by the user drawing back the handle of the Vaclok Syringe. Once the seal is created, the user irrigates the capsule of residual cortex and/or epithelial cells. The device is provided sterile (ethylene oxide).

5. Use:
The Fluid Isolation Device (FID) is a single use sterile device used to hold and seal the lens capsule, to allow irrigation of the capsular bag in an aphakic patient, in order to remove residual cortex and/or epithelial cells. The device comprises a vacuum ring with circular suction cup whose seal is activated when the user draws back on the attached syringe plunger. Irrigating solution can then be injected into the capsular bag through an internal channel, allowing removal of residual cortex and/or epithelial cells without damaging other internal structures within the eye.
Indications for use:
The Fluid Isolation Device is intended to hold and seal the lens capsule, to allow irrigation of the capsular bag in an aphakic patient, in order to remove residual cortex and/or epithelial cells. This indication for use is substantially equivalent to its predicate device.

6. Technological characteristics:
The FID is comprised of a vacuum ring with circular suction cup whose seal is activated when the user draws back on the syringe plunger. The vacuum ring and tubing which connects the vacuum ring to a lure lock (which attaches it to the syringe) is manufactured of medical grade silicone. The syringe is supplied connected to this apparatus and is a commercially available unit. All the technological characteristics are similar to the predicate device, the Milvella Perfect Capsule. The predicate device is also comprised of a vacuum ring which is connected to the identical commercially available syringe using similar silicone tubing. And the source of energy which forms the suction (i.e. the user, an ophthalmic surgeon) is identical.

7. Performance data:
Non clinical tests

a. All contact materials have been tested for biocompatibility and all results were satisfactory (Section 16 of this submission, 'Biocompatibility') and considered equivalent to the predicate device.
b. Performance equivalence was established using a side by side comparison of functional suction power over time, and all results were satisfactory (Section 19 of this submission, 'Performance Testing- Bench') and considered equivalent to the predicate device.

8. Clinical tests:
   Not required

9. Conclusions:
   The Fluid Isolation Device is substantially equivalent in safety and efficacy to the legally marketed predicate device.

Jimmy Chacko
Vice President, Regulatory Affairs
Lenstec Inc.

JUNE 25th, 2009
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

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Lenstec, Inc.
c/o Mr. Jimmy Chacko
Vice President, Regulatory Affairs
1765 Commerce Avenue N
St. Petersburg, FL 33716

Re: K091915
Trade Name: Lenstec Fluid Isolation Device
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation system
Regulatory Class: Class II
Product Code: HQC
Dated: September 23, 2009
Received: September 25, 2009

Dear Mr. Chacko:

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 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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

K091915

INDICATION FOR USE STATEMENT

510(k) Number: not yet known

Device Name: Lenstec Fluid Isolation Device

Indications for Use: The Lenstec Fluid Isolation Device is intended to hold and seal the lens capsule, to allow irrigation of the capsular bag in an aphakic patient, in order to remove residual cortex and/or epithelial cells

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

Daryl L. Kaufman

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

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