K063802

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MAY - 7 2007

510(k) Summary

Date Summary Prepared: December 20th, 2006

Lenstec Inc.
510(k) Premarket Notification Submission
Lenstec LC Injection System for STAAR Collamer Plate Intraocular Lenses
510(k) Premarket Notification Summary

Trade/Device Name: Lenstec LC Injection System for STAAR Collamer Intraocular Lens Model CC4204BF
Regulation Number: 21 CFR 886.1850
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I
Product Code: MSS

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: 2870 Scherer Drive, suite 300
      St. Petersburg, FL 33716
      Telephone Number: (727) 571-2272
      Fax Number: (727) 571-1792
   c. Contact Person: Jimmy Chacko, Vice President, Regulatory Affairs
   d. Address: 2870 Scherer Drive, suite 300
      St. Petersburg, FL 33716
      Telephone Number: (727) 571-2272
      Fax Number: (727) 571-1792
      Email: JChacko@Lenstec.com

2. Name of Device
   a. Trade Name: Lenstec LC Injection System for STAAR Collamer Intraocular Lens Model CC4204BF
   b. Common Name: Intraocular Lens guide
   c. Classification Name: Folders and Injectors, intraocular lens (IOL) (MSS, 886.4300)

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3. Substantially Equivalent legally-marketed devices:
   a. Lenstec Injection System for Tetraflex Intraocular lenses (K050638)
   b. Lenstec Injection System for Softec Injection System (K060533)

4. Device Description
   The system consists of the following components:

Cartridge	Injector	Tip Diameter (mm)	STAAR IOL Power range (D)
LC-16 w/ Silicone Cushion (SIC-01-02)	I-9011	1.6	10.5 – 34.0
LC-24 w/ Silicone Cushion (SIC-01-02)	I-9011	2.4	10.5 – 34.0

   One type of injector is provided: it is syringe based and is reusable and autoclavable. The cartridges/silicone cushion is single-use and provided sterile.

5. Use:
   The Lenstec LC Injection System is intended for use in implantation of STAAR Collamer posterior chamber intraocular lens model CC4204BF, and is used in conjunction with Lenstec LC 16 cartridge (with silicone cushion) or LC 24 cartridge (with silicone cushion).

6. Indications for use:
   The Lenstec LC Injection System is intended for use in the implantation of STAAR Collamer Intraocular Lens model CC4204BF into the capsular bag following extracapsular extraction.

7. Technological characteristics:
   The system has two major components: a reusable injector and one of two disposable cartridges (LC 16, LC 24) with a silicone cushion (SIC-01-02)
   a. the injector is manufactured of titanium and can be autoclaved
   b. the cartridge is manufactured of lubricated medical grade polypropylene and is single use
   c. the silicone tip is manufactured of medical grade polypropylene and is single use

8. Performance data:
   a. Non clinical tests
      All contact materials have been tested for biocompatibility. The system was tested with STAAR Collamer Intraocular Lens model CC4204BF

9. Clinical tests:
   Not required

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10. Conclusions:
    The Lenstec LC Injection System is substantially equivalent in safety and efficacy to the legally marketed predicate device.

Jimmy Chacko
Vice President, Regulatory Affairs
Lenstec Inc.

DECEMBER 20th, 2006
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 7 2007

Lenstec, Inc.
c/o Mr. Jimmy Chacko
Vice President, Regulatory Affairs
2870 Scherer Drive, suite 300
St. Petersburg, FL 33716

Re: K063802
Trade/Device Name: Lenstec LC Injection System for STAAR Collamer Intraocular Lens Model CC4204BF
Regulation Number: 21 CFR 886.1850
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I
Product Code: MSS
Dated: April 5, 2007
Received: April 9, 2007

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 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

M B Eydelman, MD

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

INDICATION FOR USE STATEMENT

INDICATION FOR USE

The Lenstec LC Injection System is intended for use in the implantation of STAAR Collamer Intraocular Lens model CC4204BF into the capsular bag following extracapsular extraction.

Jimmy Chacko
Vice President, Regulatory Affairs
Lenstec Inc.

DECEMBER 21, 2006
Date

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

510(k) Number K063802