1765 Commerce Ave. N. • St. Petersburg, FL 33716 • USA
Telephone: (727) 571-2272 • Fax: (727) 571-1792 • E-mail: lenstec@lenstec.com

Section 5: 510(k) Summary

Date Summary Prepared: May 25, 2012

Lenstec Inc 510(k) Summary for Premarket Notification Submission for Lenstec LC Injection System

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 Avenue North
      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

OCT 18 2013

2. Name of Device
   a. Trade name: Lenstec LC Injection System
   b. Common name: Intraocular lens injection system
   c. Regulation name: Intraocular lens guide
   d. Regulatory class: Class I, reserve
   e. Product code: MSS
   f. Regulation number: 21 CFR 886.4300

3. Substantially Equivalent legally-marketed device:
   a. Lenstec Injection System for STAAR Collamer Plate Intraocular Lens (K063802)

510(k) Number (if known):_____

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

Cartridge with silicone cushion	IOL	Injector	Tip Diameter (mm)	Lenstec IOL Power range (D)
LC 16	Softec HD	I-9011S	1.6	5.0 – 26.0
	Softec I			
	Softec HD PS			
LC 1620	Softec HD	I-9011S	1.6	5.0 – 26.0
	Softec I			
	Softec HD PS			
LC 2420	Softec HD	I-9011S	2.4	5.0 – 36.0
	Softec I			
	Softec HD PS			

One type of injector is provided: it is syringe based and is reusable and autoclavable. One type of lens loader is provided, which 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 the implantation of the Softec HD, Softec I and Softec HD PS model Lenstec IOLs, as well as any IOL which has indicated for its use in its approved labeling, into the capsular bag following extracapsular extraction. The predicate device was comprised of the nearly identical components.

Lenstec has added a pair of cartridges to the LC Injection system (LC 1620 and LC 2420). These two additional cartridges only differ from the originals in that their tips are angulated to 20°, as opposed to the LC 16, which has a 45° tip.

This submission also removes the LC24 model cartridge.

The only changes in this injection system are
a) the modified indication for inclusion for use of the Lenstec model IOLs identified above, and removal of STAAR Collamer Plate IOL previously indicated for use with
b) Change in the models of cartridge validated for use
c) the replacement of the lens fork loader with the lens loader (this is discussed in greater detail elsewhere in this submission)

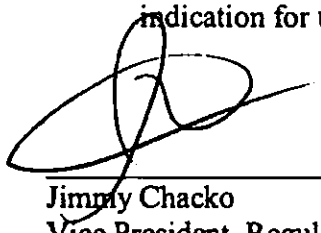
6. Indications for use:
The Lenstec LC Injection System is intended for use in the implantation of the Softec HD, Softec I and Softec HD PS model Lenstec IOLs, as well as any IOL which has indicated for its use in its approved labeling, into the capsular bag following extracapsular extraction.

7. Technological characteristics:
   The system has three major components: a reusable injector, a reusable lens loader and one of three disposable cartridges (LC 16, LC 1620, LC 2420) with a silicone cushion (SIC-01-02)
   a. the injector is manufactured of titanium and can be autoclaved
   b. the lens loader is manufactured from plastic and can be autoclaved
   c. the cartridge is manufactured of medical grade polypropylene and is for single use
   d. the silicone tip is manufactured of medical grade silicone and is for single use

8. Performance data:
   a. Non clinical tests
      All contact materials have been tested for biocompatibility, with satisfactory results. Also, the system was tested with each of the following Lenstec intraocular lens models with satisfactory results: Softec HD, Softec I and Softec HD PS.

9. Clinical tests:
   Not required

10. Conclusions:
    The Lenstec LC Injection System is substantially equivalent to the legally marketed predicate device, and the included testing validates the expanded indication for use.



Jimmy Chacko
Vice President, Regulatory Affairs
Lenstec Inc.

25 MAY 12
Date

510(k) Number (if known):_____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 18, 2013

Lenstec, Inc.
% Mr. Hans-Gerd Evering
Lead Technical Reviewer
British Standards Institute (BSI)
Kitemark Court, Davy Avenue
Knowlhill, Milton Keynes MK5 8PP, UK

Re: K122848
Trade/Device Name: Lenstec LC Injection System
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular lens guide
Regulatory Class: Class I (reserve)
Product Code: MSS
Dated: October 2, 2013
Received: October 4, 2013

Dear Mr. Evering:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact 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/MedicalDevices/ResourcesforYou/Industry/default.htm. 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/MedicalDevices/Safety/ReportaProblem/default.htm 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for 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

Section 4: Indications for Use Statement

510(k) Number (if known): not yet known

Device Name: Lenstec LC Injection System

Indications for Use: The Lenstec LC Injection System is intended for use in the implantation of the Softec HD, Softec I and Softec HD PS model Lenstec IOLs, as well as any IOL which has indicated for its use in its approved labeling, into the capsular bag following extracapsular extraction

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)

Tieuvi H. Nguyen
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Section 4: pg 1 of 1
510(k) Number (if known):_____