DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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November 29, 2016

Lenstec Inc.
Mr. Jimmy Chacko
Vice President, Regulatory Affairs
1765 Commerce Ave. N.
St. Petersburg, Florida 33716

Re: K161776
Trade/Device Name: Lenstec LC Injection System
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I
Product Code: MSS
Dated: November 2, 2016
Received: November 3, 2016

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. 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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Kesia Alexander

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Lenstec LC Injection System

Indications for Use *(Describe)*
Lenstec's LC Injection System is intended for use in the implantation of the Softec HD, Softec I, Softec HDO, Softec HDM and any approved IOL in which the labeling specifies use of this injector (s) to insert the lens into the capsular bag following extracapsular extraction.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 6: 510(k) Summary

Date Summary Prepared: June 17th, 2016

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
      Additional Contact Person: Sheila Baker, Clinical Research Manager
      Email: SBaker@Lenstec.com

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 Intraocular Lens delivery (K122848)

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

CART SERIES CARTRIDGE CHART				
Cartridge with silicone cushion	IOL	Injector	Tip Diameter (mm)	Lenstec IOL Power range (D)
CART 20S	SOFTEC HD	I-9011S I-9012 I-9012 FS	1.6	5.0 - 26.0
	SOFTEC I			
	SOFTEC HDO			SOFTEC HDO 5.0 - 22.0
CART 45S	SOFTEC HD	I-9011S I-9012 I-9012 FS	1.6	5.0 – 26.0
	SOFTEC I			
	SOFTEC HDO			
CART M	SOFTEC HDM	I-9011S I-9012 I-9012 FS	1.7	5.0 – 36.0

Three types of injectors are provided: they are syringe based and reusable and autoclavable. One type of lens loader is provided, which is reusable and autoclavable. The cartridges/silicone cushion are single-use and are provided sterile.

5. Use:
Lenstec's LC Injection System is intended for use in the implantation of the Softec HD (P090022), Softec I (P090022/S001), Softec HDO (P090022/S011), Softec HDM (P090022/S026) and any approved IOL in which the labeling specifies use of this injector to insert the lens into the capsular bag following extracapsular extraction. The predicate device was comprised of the nearly identical components.

Lenstec seeks to have cleared the addition of a surface treatment technology, LubriMATRIX™, to Cart 45S, Cart 20S and Cart M cartridges as well as a change of material due to the vendor discontinuing the current material. We also request the addition of two new lens injectors, which have barrels that are now threaded instead of smooth, allowing for a twisting motion to advance the plunger into the cartridge.

The only changes in this injection system are
a) the modified indication for inclusion for use of the Softec HD, Softec I, both through K122848. Softec HDO and HDM through this current application.

b) additional new cartridges; Cart 45S, Cart 20S, Cart M
c) The addition of surface treatment technology (LubriMATRIX™) on all "Cart" models (Cart 45S, Cart 20S, Cart M)
d) A slight material change from the Atofina Polypropylene 7823MZ to the Total 7823M Polypropylene. The only reason for the change is that the vendor has discontinued the 7823MZ. The only difference is that the 7823M does not contain an antistat.

6. Indications for use:
Lenstec's LC Injection System is intended for use in the implantation of the Softec HD, Softec I, Softec HDO, Softec HDM and any approved IOL in which the labeling specifies use of this injector to insert the lens 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 (Cart 45S, Cart 20S, Cart M) with a silicone cushion (SIC-01-02). Discussed here are the characteristics of the changes only. The lens loader and silicone cushion have not had any changes and are still identical to those cleared under K122848.

   a. The proposed injectors (I-9012 and I-9012 FS) both have threaded barrels instead of the smooth barrel ("syringe like") injection of the I-9011S. Both the I-9012 and I-9012 FS advance the IOL through the cartridge once the user twists the injector knob until the IOL is delivered into the eye. The I-9011S injector advances the IOL through the cartridge once the user pushes the injector knob until the IOL is delivered into the eye.
   b. The surface treated cartridges (Cart 45S, Cart 20S, Cart M) have LubriMATRIX™ applied for lubricity.
   c. The proposed cartridge is manufactured of medical grade polypropylene and is for single use as in the cleared K122848, however, a material change is necessary due to the vendor discontinuing the polypropylene we currently purchase (7823MZ). The proposed material is now 7823M without the antistat that the 7823MZ had.

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 HDO and Softec HDM. Due to the similarities of the Softec HD and Softec 1 IOL design, the Softec 1 will not undergo performance testing of its own. Based on the overall design shape of the Softec HD to the Softec 1, equivalence is expected and we can therefore include the Softec 1 as part of the indications for use as in the previously cleared K122848.

The Cart M was successfully tested with the Softec HDM and can also be included as part of the indications for use statement. Furthermore, the cartridges tested passed the USP <789> Particulate Matter in Ophthalmic Solutions- Light Obscuration Tests.

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.

17 June 16
Date