



Food and Drug Administration
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October 30, 2015

STAAR Surgical Company
Mr. Jack Coggan
Director of Regulatory Affairs
1911 Walker Avenue
Monrovia, CA 91016

Re: K152357
Trade/Device Name: MicroSTAAR[®] Injector System Cartridges
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I
Product Code: MSS, KYB
Dated: September 29, 2015
Received: September 30, 2015

Dear Mr. Coggan:

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 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



MicroSTAAR INJECTOR SYSTEM (MSI) CARTRIDGE SFC-45

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K152357

Device Name: MicroSTAAR® Injector Cartridge

The MicroSTAAR® Injector System (MSI) is a device intended to fold and insert STAAR® Surgical Company Collamer® phakic and aphakic 1-piece intraocular lenses for surgical placement into the human eye.

Prescription Use _____ AND/OR Over the Counter Use ___
(Part 21 CI-1 (801 Subpart D))

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



MicroSTAAR INJECTOR SYSTEM (MSI) CARTRIDGE SFC-45

510 (k) SUMMARY

Submitter Information

STAAR Surgical Company
Contact: Jack Coggan
Director of Regulatory Affairs
1911 Walker Avenue
Monrovia, California 91016
Phone: 626.303.7902 ex. 2616
Fax: 626.303.2962

Company Registration Number

2023826

Submission Correspondent

STAAR Surgical Company
Contact: Jack Coggan
Director of Regulatory Affairs
1911 Walker Avenue
Monrovia, California 91016
Phone: 626.303.7902 ex. 2616
Fax: 626.303.2962

Date Summary Prepared

September 16, 2015

Classification Name

Lens, Guide, Intraocular
Class I KYB 21 CFR 886.4300
Folders and Injectors, Intraocular
Lens (IOL)
Class I MSS 21 CFR 886.4300

Common/Usual Name

Intraocular Lens Injector Cartridge

Device Trade Name

MicroSTAAR® Injector System
Model: SFC 45

The primary device used for comparison in this summary is MicroSTAAR® Injector System Cartridges (K101782).

INTENDED USE

The intended use of the MSI Cartridge in this submission is substantially equivalent to the intended use of the predicate cartridges (K101782). Please refer to the Directions for Use for the predicate device, which will also be used with the proposed MSI cartridge.



MicroSTAAR INJECTOR SYSTEM (MSI) CARTRIDGE SFC-45

The intended use of the modified device, as described in its labeling has not changed as a result of this modification. The MicroSTAAR® Injector System is intended to fold and insert STAAR Surgical Company Collamer® phakic and aphakic 1-piece intraocular lenses for surgical placement in the human eye.

DESCRIPTION (Device)

The MicroSTAAR® Injector System Cartridge (MSI Cartridge) is designed to facilitate the loading, folding and delivery of Collamer® phakic and aphakic intraocular lenses (ICL/IOL) into the human eye through a small incision. There is one model of MSI Cartridge in this submission, SFC-45 cartridge. The SFC-45 Cartridge is designed to lock into a corresponding MicroSTAAR® Injector System.

The cartridge has a loading area on one end and a tapered tip on the other. The SFC-45 has a funnel shape, with exposed flat loading areas, and was designed to work with the Collamer® 1-piece lenses manufactured by STAAR Surgical.

The new polypropylene material used for manufacturing the SFC-45 cartridges is substantially equivalent to that of the predicate device's polypropylene material. The proposed material will be supplied by the same supplier in Japan. The material will be shipped to STAAR Monrovia, USA, to be forwarded to a molding contractor in the USA. The molded MSI cartridge will be returned to STAAR Monrovia for the rest of the manufacturing process. There will be no changes to the in-process or the final release specifications and all manufacturing processes of the MSI Cartridges will be the same as those of the predicate cartridges.

The product description for the MSI Cartridge is substantially equivalent to that of the predicate devices.

TECHNOLOGICAL CHARACTERISTICS

The MSI Cartridge has substantially equivalent technological characteristics to the predicate device. Refer to **Table 7** in the following section, entitled Device Comparison, for a summation of the technological characteristics such as design.

MicroSTAAR INJECTOR SYSTEM (MSI) CARTRIDGE SFC-45

Table 7
Device Comparison

Description	Predicate MicroSTAAR Injector System Cartridges	New MicroSTAAR Injector System Cartridge (SFC-45)
510(k)	K101782	N/A
Models	SFC 45	SFC 45
Product Description	System is designed to facilitate the loading, folding and delivery of an intraocular lens (ICL) into the human eye through a small incision.	Identical
Intended Use	Intended to fold and insert STAAR Surgical Company 1-piece Collamer® intraocular lenses for surgical placement in the eye.	Identical
Design Control Activities	Single use cartridge to be used in conjunction with appropriate injector system and 1-piece Collamer® lenses for surgical placement of lens into eye.	Identical
Materials	Cartridge is manufactured from Polypropylene MG05 (which contains GMS) and polypropylene MG03 (which does not contain GMS) purchased from a supplier in Japan.	Cartridge is manufactured from a new polypropylene MG03BDS formulation (which contains GMS) material is purchased from the same supplier in Japan
Manufacturing	Utilization of contract manufacturers for polypropylene material and cartridge molding.	Identical.
Operating Principle	Depending on the cartridge the ICL is either loaded into the loading area and folded shut, or it is pressed forward towards the tip.	Identical
Packaging	Cartridge is placed in a tray, sealed with Tyvek lid and label is placed on a Tyvek pouch. utilizing STAAR Monrovia's USA packaging supplier	Identical
Sterilization	Sterile Ethylene Oxide (EtO)	Identical
Manufacturer	STAAR Surgical Company	Identical



MicroSTAAR INJECTOR SYSTEM (MSI) CARTRIDGE SFC-45

PERFORMANCE DATA:

The non-clinical tests summary that was performed to validate and verify the change in the polypropylene formulation is summarized below:

Biocompatibility Study:

The SFC Cartridge manufactured using the new GMS (MG03BDS) passed the biocompatibility study that Namsa Laboratory tested for the cytotoxicity tests, sensitization test and intraocular irritation test. The cytotoxicity test article extract showed no evidence of causing cell lysis or toxicity. The sterilization test article extract showed no evidence of causing delayed dermal contact sensitization in the guinea. The intraocular irritation test showed there were no differences in ocular observations between eyes treated with test article extract and those treated with the control vehicle. It is concluded that the SFC45 cartridge material used in the new GMS material (MG03BDS) is biocompatible.

Feasibility Test:

The feasibility test results of the cartridges manufactured using the new MG03BDS material were found to be substantially equivalent to the cartridges manufactured using the current material. The SFC-45 cartridge manufactured with the new MG03BDS material successfully delivered the lenses without any damage to the lenses or the cartridge. Therefore, it was concluded that the MG03BDS material is an adequate replacement for the current material.

Fourier-transform infrared Fourier-transform infrared spectroscopy (FTIR):

An analysis of the new polypropylene formulation change was performed using the Fourier-transform infrared spectroscopy (FTIR). The FTIR resulting spectra showed the typical makeup for the polypropylene copolymer material. The main difference between all materials was related to the amount of additives.

Shelf-life:

Shelf-life testing of the SFC-45 cartridge after 1 month and 2 months accelerated aging indicated the cartridges manufactured with the new MG03BDS material are comparable to the cartridges manufactured using the current material and passed within the manufacturer's specifications. The delivery of the lenses was smooth and there was no damage to the cartridges or lenses.

Sterilization:

Sterilization study indicated that cartridges sterilization was successful and provided a minimum sterility assurance level of 1×10^{-6} (probability of less than one non-sterile unit out of each one million units sterilized.). All biological indicators indicated that bacteriostatic/fungistatic characteristics were not associated with the product. EO/ECH residuals were negligible.