K101134

AUG - 9 2010

510(k) SUMMARY

Pursuant to 510(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and in accordance with 21 CFR § 807.92.

Submitter Information:

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Submission Correspondent:

Medicel AG
Contact: John Coggan
(Official Correspondent)
STAAR Surgical
1911 Walker Ave
Monrovia, CA 91016
USA

Date Summary Prepared: April 5, 2010

Classification Name: Folders and Injectors, Intraocular Lens (IOL) (Class I) – MSS 21 CFR 886.4300

Common/Usual Name: Intraocular Lens Guide

Device Trade Name: Visian® nanoPOINT™ 2.0 Injector System

Equivalent legally-marketed devices: K092023, IOL Intraocular Injector Set, Medicel AG (Navijet Sub2-1P Injector Set)

1. Intended Use:

The Visian® nanoPOINT™ 2.0 Injector System is a device intended to fold and insert STAAR Surgical Collamer® Phakic One Piece Intraocular Lenses, Model Visian® ICL, for surgical placement in the human eye.

2. Description:

The Visian® nanoPOINT™ 2.0 Injector System is a sterile, single-use device intended to fold and insert a STAAR Surgical Collamer® Phakic One Piece Intraocular Lens, Model Visian® ICL through surgical procedure in a human eye. The system provides a tubular pathway through a corneal incision allowing delivery of a phakic IOL into the human eye.

3. Technological Characteristics:

The Visian® nanoPOINT™ 2.0 Injector System has substantially equivalent technological characteristics to the predicate devices. Refer to **Table 1** in the following section, entitled *Comparison Analysis*, for a summation of technological characteristics such as design, dimensional specifications, and material. There are no differences in any of the technological characteristics of this device as compared to the cleared predicate device and therefore the safety and effectiveness of this device are not compromised.

4. Comparison Analysis:

The overall design of this Visian® nanoPOINT™ 2.0 Injector System is the same as the predicate device since it is the same injector. The indications for use and labeling were modified to clearly specify the lens model for which it is intended.

Performance Data

(1) Non Clinical Tests: All materials have been tested for biocompatibility. These tests were performed in the previously cleared device, the K070669 injector set, which was substantially equivalent to K092023 and therefore equivalent to the newly submitted 510(k) device. These tests were all acceptable.

The validation (non-clinical) tests for the previously cleared K092023, Navijet Sub2-1P IOL Injector Set, are the same for this newly submitted device, the Visian® nanoPOINT™ 2.0 Injector System, since it is the same injector and it is intended for the folding and insertion of the same lens. See **Table 1** for a comparison of the new and the previous K092023, Navijet Sub2-1P IOL Injector Set.

Shelf Life for the previously submitted devices was set at three years based on tests performed on equivalent injectors. This new device will have the same shelf life.

2) Clinical Tests: (Not required)

3) Conclusions: In conclusion the newly submitted device is as safe, as effective and performs as safely and effectively as the legally marketed device as it is

the same device and there were no changes to the technological characteristics of the device.

Feature	Visian® nanoPOINT™ 2.0 Injector System	K092023	Substantially Equivalent
Product Description	This Injector and Cartridge System is a sterile, single-use device intended to fold and insert a STAAR Surgical Collamer® phakic one piece intraocular lens, Model Visian® ICL through surgical procedure in a human eye. The system provides a tubular pathway through a corneal incision allowing delivery of a phakic IOL into the human eye.	Identical	Yes
Intended Use	The Visian® nanoPOINT™ 2.0 Injector System is a device intended to fold and insert a STAAR Surgical Collamer® phakic one piece intraocular lens, Model Visian® ICL, for surgical placement in the human eye.	The Naviject SUB2-1P IOL Injector and Cartridge Set for intraocular lenses is indicated for the insertion only of models of intraocular lenses that allow use of this injector in their approved labeling.	Yes, the only difference is in the inclusion of the specific lens name for which it is intended
Design	This device has 3 basic components: a syringe type injector with a silicone cushion tip plunger, a 33° bevel down cartridge tip and a loading block.	Identical	Yes
Materials	Plastic materials: ABS, Polydimethilsiloxane (Silicone) and Polypropylene with GMS additive	Identical	Yes
Mechanical Safety	Validated for STAAR Surgical Collamer® Phakic One Piece Intraocular Lenses, Model Visian® ICL (V08-138)	Identical	Yes
Manufacturing	Per internal operating procedures	Identical	Yes
Operating Principle	A phakic IOL is loaded into the cartridge, then pushed through the cartridge and delivered into a human eye through a 2.2 mm surgical incision.	Identical	Yes
Packaging	Blister trays with pre-printed labeling on Tyvek material lids and boxes	Blister trays with labeled Tyvek material lids and labeled boxes	Yes
Biocompatibility	Injector materials are the same as the previously cleared K070669 IOL injector. Biocompatibility tests for that injector were acceptable.	Biocompatibility for K092023, substantially equivalent to K070669, shall be identical to the newly submitted device	Yes
Shelf Life	Three years	Identical	Yes
Sterility	Sterile (EO)	Identical	Yes
Manufacturer	Medicel AG	Medicel AG	Yes

Table 1: Summary of Design Comparison

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Medicel AG
c/o Mr. John Coggan
Director of Regulatory Affairs
STAAR Surgical Company
1911 Walker Avenue
Monrovia, CA 91016

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Re: K101134
Trade/Device Name: Visian® nanoPOINT™ 2.0 Injector System
Regulation Number: 21 CFR 886.4300
Regulation Name: Folders and Injectors, Intraocular Lenses
Regulatory Class: Class I (reserve)
Product Code: MSS
Dated: July 14, 2010
Received: July 16, 2010

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 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/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,

Kevia Alexander

for 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

Indications for Use Statement

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510(k) Number (if known): K101134

Device Name: Visian® nanoPOINT™2.0 Injector System

The Visian® nanoPOINT™ 2.0 Injector System is a device intended to fold and insert STAAR Surgical Collamer® Phakic One Piece Intraocular Lenses, Model Visian® ICL, for surgical placement in the human eye.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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