K141091

MAY 2 8 2014

Rayner

510(k) Summary

This summary document has been prepared in accordance with section 21 CFR 807.92(c).

The submitter of the 510(k) is:

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Date Summary Prepared: May 27, 2014

Subject Device

Trade Name:	RaySert PLUS Small Incision Single Use Soft-Tipped Injector
Classification Panel:	Ophthalmic
Product Code:	MSS
Common Name:	Folders and Injectors, Intraocular Lens (IOL)
Classification Name:	21 CFR 886.4300
Device Class:	Class I

Predicate Device

The predicate devices are the Single Use Soft Tipped Disposable Injector (Model: R-INJ-04), and the Raysert Single Use Soft Tipped Small Incision Disposable Injector (Model: R-INJ-04/18), both with 510(k) number K132002, concurrence date March 27, 2014.

Device Description

The RaySert PLUS Small Incision Single Use Soft-Tipped Injector is a device for folding and delivering Rayner C-flex intraocular lenses (models 570C and 970C), and other IOLs indicating the use of the RaySert PLUS in their approved labeling into the eye. The RaySert PLUS consists of a syringe shaped body and nozzle, with a soft tipped plunger, and a loading bay closed in use with a mobile flap. The RaySert PLUS is a sterile, disposable plastic device, with a narrow diameter circular lumen through which the IOL can be introduced into the eye in a single continuous action. RaySert PLUS is designed for single use only.

Indication for Use

The RaySert PLUS Small Incision Single Use Soft-Tipped Injector (Model R-INJ-10) is intended to be used to compress and insert into the capsular bag only those intraocular lenses that allow the use of these injectors in their approved labeling.

With the exception of the model name and number, this is the same indication for use as the predicate device.

Comparison of Devices

Please see the table below for a comparison of the subject device to the predicates.

Characteristic	Predicate K132002 (Models R-INJ-04 and R-INJ-04/18)	Subject Device (Model R-INJ-10)
Indication for Use	The single use disposable injectors (Model R-INJ-04, and Model R-INJ-04/18) are intended to be used to compress and insert into the capsular bag only those intraocular lenses that allow the use of these injectors in their approved labeling.	The single use disposable injector (Model R-INJ-10) is intended to be used to compress and insert into the capsular bag only those intraocular lenses that allow the use of these injectors in their approved labeling.
Contraindications	1. Vitreous in the anterior chamber. 2. Zonular insufficiency.	1. Vitreous in the anterior chamber. 2. Zonular insufficiency.
Materials	Barrel: Polypropylene Flap: Polypropylene Nozzle: Polypropylene Plunger tip: TPE, Santoprene Plunger shaft: Polypropylene Guide Bush (x 2): Polypropylene	Barrel: Polypropylene Flap: Polypropylene Nozzle: Polypropylene Plunger tip: TPE, Santoprene Plunger shaft: Polypropylene Guide Bush (x 2): Polypropylene
Number of Uses	Single Use	Single Use
Sterility	Supplied Sterile	Supplied Sterile
Sterilization Method	Ethylene Oxide	Ethylene Oxide
Sterility Assurance Level	10^{-6}	10^{-6}
Shelf Life	5 Years	2 Years (with protocol in place to extend to 5 years as testing is completed)

Conclusion

The Rayner Injectors described in this submission are substantially equivalent to the predicate devices.

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

May 28, 2014

Rayner Intraocular Lenses, Ltd.
% Dr. Juliette E. Cook
Director of Quality and Regulatory Affairs
1-2 Sackville Trading Estate
Sackville Road
Hove
East Sussex
BN3 7AN
United Kingdom

Re: K141091
Trade/Device Name: Single Use Soft Tipped Disposable Injector (Model R-INJ-10)
Regulation Number: 21 CFR 886.4300
Regulation Name: Folders and Injectors, Intraocular Lens (IOL)
Regulatory Class: Class I
Product Code: MSS
Dated: April 23, 2014
Received: April 28, 2014

Dear Dr. Cook:

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

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)*
K141091

Device Name
Rayner RaySert PLUS Small Incision Single Use Soft-Tipped Injector (Model R-INJ-10)

Indications for Use *(Describe)*
The RaySert PLUS Small Incision Single Use Soft-Tipped Injector (Model R-INJ-10) is intended to be used to compress and insert into the capsular bag only those intraocular lenses that allow the use of these injectors in their approved labeling.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Andrew Yang -S
2014.05.23 15:41:47 -04'00'

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