K091507

Rayner

Rayner Intraocular Lenses Limited
Sackville Road
Hove
East Sussex
BN3 7AN
England

Telephone +44 (0) 1273 205401
Fax +44 (0) 1273 324022
www.rayner.co

DEC - 4 2009

510(k) Summary as required by 21 CFR 807.92

Submitted by

Rayner Intraocular Lenses Limited
Address as letterhead
Establishment registration: 9611165

Contact person:
Roy Kernaghan
Regulatory Affairs Manager
Telephone # 0044-1273-740619
Fax # 0044-1273-324623
Email: roykernaghan@rayner.com

Summary prepared on May 1st, 2009

Device Information

- Trade/Proprietary Name: Rayner Single Use Small Incision Disposable Injector R-INJ-04/18
- Common Name: Rayner Single Use Small Incision Injector
- Classification: Product Code is MSS. CRF section is TITLR 21. Part 886. Subpart E. Sec. 886.4300 Intraocular Lens guide. Device is Class I. Classification panel is Ophthalmic

Information on devices to which substantial equivalence is claimed

- 510(k) Number: K062512
- Trade or Proprietary or Model Name: Rayner Single Use Soft Tipped Disposable injector R-INJ-04
- Manufacturer: Rayner Intraocular Lenses Limited

Intended Use

The single use small incision disposable injector (model number R-INJ-04/18 is intended to be used to compress and insert into the capsular bag only those Intraocular Lenses that allow use of this injector in their approved labelling.

Description of the device that is subject to of this application, including an explanation of how the device functions, basic scientific concepts, scientific, physical and performance characteristics (design, material, physical properties)

The single use small incision disposable injector (model number R-INJ-04/18 is intended to be used to compress and insert into the capsular bag only those Intraocular Lenses that allow use of this injector in their approved labelling. It is designed to mechanically fold the lens and insert it into the eye during normal, small incision (1.8mm) cataract surgery.

INJECTOR LOADING is described as follows:
Aseptically transfer the injector to the sterile field by tipping it from the tray. Fully retract the plunger ensuring the tip does not protrude into the loading bay. Open the loading bay flap fully to 90o and sparingly apply a commercially available viscoelastic inside the nozzle and to both grooves of the loading bay. Balanced salt solution alone should not be used as a lubricant. Carefully peel back the foil lid of the lens blister. Gently lift out the lens using parallel tipped, non serrated forceps e.g. Kelman-McPherson. Rinse the Intraocular Lens with sterile balanced salt solution. Position the lens in the injector loading bay in a "reverse S" configuration. Ensure that the nearest edge of the optic is securely under the edge (lip) of the barrel. Hold open the flap and press down on the lens with closed forceps to ensure that the furthest edge of the optic is securely under the edge (lip) of the flap. Ensure that the haptics are completely within the loading bay. While keeping the lens in position with open forceps, gently close the flaps of the injector ensuring that no part of the optic or haptics is trapped, before locking the flaps firmly together. Visually observe that the lens is symmetrically folded within the loading bay. Advance the plunger in a slow controlled manner. Anticipate an initial slight resistance. Excessive resistance could indicate a trapped lens. Observe that the lens stays symmetrically folded within the nozzle. When the lens exits the nozzle, stop depressing the plunger. The plunger is only to be depressed once.

The small incision injector (model number R-INJ-04/18 is a plastic single use disposable device.

The injector components barrel, flap, nozzle, bush and sleeve are made of polypropylene. The plunger is made of polycarbonate. The injector is transparent and the plunger is white.

Summary of Testing

The Single Use Soft Tipped Disposable Injector R-INJ-04/18 was designed, developed and tested according to written procedures. Mechanical testing was completed to ensure that the injector functioned according to the requirements. The test results support a determination of substantial equivalence.

Conclusions

The Single Use Soft Tipped Disposable Injector R-INJ-04/18 has exactly the same intended use as the predicate device, using a smaller incision and essentially has identical technological characteristics. Minor changes in the dimensions of the injector nozzle do not raise any new questions regarding safety of effectiveness of the device. The R-INJ-04/18 Injector performs as intended and presents with no unacceptable risks to the intended patient population or end user. The R-INJ-04/18 is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Rayner Intraocular Lenses Limited
c/o Mr. Roynan H. Kernaghan
Sackville Road
Hove
East Sussex
BN3 7 AN
England

DEC - 4 2009

Re: K091507
Trade/Device Name: Rayner Single Use Soft Tipped Small Incision Disposable Injector R-INJ-04/18
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: II
Product Code: MSS
Dated: October 1, 2009
Received: October 5, 2009

Dear Mr. Kernaghan:

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.

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kesia 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

510(k) Number (if known): K091507

Device Name: **Rayner Single Use Soft Tipped Small Incision Disposable Injector R-INJ-04/18**

Indications For Use:

Statement of Indications for use

"The disposable single use soft tipped small incision injector (model number R-INJ-04/18) is intended to be used to compress and insert into the capsular bag only those IOL models that allow use of this injector in their approved labelling."
Federal U.S. Law restricts this device to sale by, or on the order of a physician.

Prescription Use_____Yes__✓ AND/OR Over-The-Counter Use____No._✓

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anna Pastel

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

510(k) Number K091507
