July 26, 2018

RxSight, Inc.
Maureen O'Connell
Vice President, Clinical/Regulatory Affairs
100 Colombia
Aliso Viejo, California 92656

Re: K181401
Trade/Device Name: RxSight Insertion Device
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I
Product Code: MSS
Dated: May 25, 2018
Received: May 29, 2018

Dear Maureen O'Connell:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Malvina 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)*
K181401

Device Name
RxSIGHT Insertion Device

Indications for Use *(Describe)*
The RxSight Insertion Device is indicated for the folding and insertion of a 3-piece silicone, intraocular lens into the human eye through a surgical incision. The RxSight Insertion Device is only for the insertion of the Bausch & Lomb LI61A0 IOL and IOL models validated for use with this device in IOL 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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1.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(a).

APPLICANT:	RxSight, Inc. 100 Columbia Aliso Viejo, CA 92656
CONTACT PERSON:	Maureen O'Connell Vice President Clinical and Regulatory moconnell@rxsight.com Tel: (978) 207-1245
DATE SUMMARY PREPARED:	July 17, 2018
TRADE NAME:	RxSight Insertion Device
COMMON NAME:	IOL Injector
CLASSIFICATION NAME:	Folders and Injectors, Intraocular Lens (IOL)
DEVICE CLASSIFICATION:	Class I; 21 CFR 886.4300
PRODUCT CODE:	MSS
PREDICATE DEVICES:	K151102, Bausch + Lomb Injector System K172228, pioli™ IOL Delivery System

1.1 DEVICE DESCRIPTION

The RxSight Insertion Device is a two-part IOL injector device comprised of a re-usable handheld titanium injector, and a single use, non-preloaded disposable polypropylene cartridge intended to be used to fold and insert the intraocular lenses into the eye through a small incision.

1.2 INDICATIONS FOR USE

The RxSight Insertion Device is indicated for the folding and insertion of a 3-piece silicone, intraocular lens into the human eye through a surgical incision. The RxSight Insertion Device is only for the insertion of the Bausch & Lomb LI61A0 and IOL models validated for use with this device in IOL approved labeling.

1.3 TECHNOLOGICAL CHARACTERISTICS COMPARISON

The technical features of the RxSight Insertion Device and predicate devices are substantially equivalent. A comparison of the technological characteristics of these devices is provided in the table below.

	RxSight Insertion Device Proposed Device	Bausch + Lomb Injector Set K151102 Predicate Device	AST Products pioli IOL Delivery System K172228 Predicate Device
Product Code	MSS	MSS	MSS
Intended Use	Intraocular Lens Delivery	Intraocular Lens Delivery	Intraocular Lens Delivery
Indications for Use	The RxSight Insertion Device is indicated for the folding and insertion of a 3-piece silicone, intraocular lens into the human eye through a surgical incision. The RxSight Insertion Device is only for the insertion of the Bausch & Lomb LI61A0 and IOL models validated for use with this device in IOL approved labeling.	The Bausch + Lomb Injector System is indicated for the folding and insertion of the Bausch + Lomb intraocular lenses cleared or approved for use with this IOL Injector system.	The pioli IOL Delivery system is a single-use, sterile device intended to insert a single-piece foldable intraocular lens (IOL) into the human eye through a surgical procedure. The system provides a tubular pathway for lens implantation through an incision. The pioli IOL Delivery System is only for the insertion of the Lenstec Softec I IOL and IOL models validated for use with this device as indicated in the IOL approved labeling.
Operating Principle	IOL placed in loading cartridge. Cartridge snapped into the handpiece. Screw plunger advances the IOL through the cartridge which folds the IOL and advances it into the eye.	IOL placed in loading cartridge. Cartridge snapped into the handpiece. Screw plunger advances the IOL through the cartridge which folds the IOL and advances it into the eye.	Cartridge is back loaded into the injection system that delivers the IOL through the cartridge and into the eye
Pre-loaded IOL	No	No	No
Material (Injector)	Titanium	Titanium	Polypropylene
Material (cartridge)	Polypropylene	Polyamide	
Cartridge Coating	LubriMATRIX™	Hydrophilic coating (Medicoat A)	LubriMATRIX™
How Supplied (Reusable/Single Use)	Handpiece - Reusable Cartridge - Single Use, supplied sterile	Handpiece - Reusable Cartridge - Single Use, supplied sterile	Handpiece - Single Use, disposable, supplied sterile Cartridge - Single Use, disposable, supplied sterile
Method of Sterilization	Handpiece - Autoclave Cartridge - Ethylene Oxide to SAL 10-6	Handpiece - Autoclave Cartridge - Ethylene Oxide to SAL 10-6	Ethylene Oxide to SAL 10-6

1.5 BRIEF SUMMARY OF PERFORMANCE TEST RESULTS

The descriptive characteristics are well-defined and adequate to ensure equivalence of the RxSight Insertion Device with the predicate device. Additionally, the proposed device was evaluated for biocompatibility, sterilization, cleaning, sterilization residuals, shipping and handling and performance bench testing. The cleaning and sterilization cycle was validated in accordance with *"Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff"* and covered both manual and automated cleaning processes described in the labeling for the RxSight Insertion Device. The EO sterilization cycle for the cartridge was validated in accordance with ANSI/AAMI/ISO 11135 to ensure a sterilization assurance level (SAL) of 10^{-6}. The device will be labeled with an expiration date of 6 months from the date of sterilization.

Performance testing of the RxSight Insertion Device included pre- and post-injection evaluation of two IOLs in accordance with ISO 11979-3:2012 surgical manipulation – recovery of properties. Specifically, mechanical dimensions and sagitta were verified after the lens delivery and compared to the measurements performed prior to the lens delivery per ISO 11979-3:2012. Similarly, optical properties overall surface and bulk homogeneity were tested pre and post lens injection per ISO 11979-2:2014.

1.6 CONCLUSION

The RxSight Insertion Device meets all product design requirements and applicable standards and embodies technological characteristics similar to the predicate devices and therefore has been shown to be substantially equivalent to the predicate device and is safe and effective for use.