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

Re: K192926
Trade/Device Name: RxSight Insertion Device
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular lens guide
Regulatory Class: Class I, reserved
Product Code: MSS
Dated: December 21, 2019
Received: December 23, 2019

Dear Ms. 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 Tieuvi Nguyen, Ph.D.
Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192926

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 intended for the insertion of the RxSight Light Adjustable Lens, 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 Affairs moconnell@rxsight.com Tel: (978) 207-1245
DATE SUMMARY PREPARED:	January 10, 2020
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 DEVICE:	RxSight Insertion Device, K181401

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 intended for the insertion of the RxSight Light Adjustable Lens, the Bausch & Lomb LI61A0 IOL 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, both predicate and proposed, are the same as no modifications to these features are proposed in this 510(k) Premarket Notification. A comparison of the technological characteristics of the proposed and predicate devices is provided in the table below.

	RxSight Insertion Device Proposed Device	RxSight Insertion Device Predicate Device (K181401)
Product Code	MSS	MSS
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 intended for the insertion of the RxSight Light Adjustable Lens, the Bausch & Lomb LI61A0 IOL and IOL models validated for use with this device in IOL approved labeling.	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
Operating Principle	An IOL is placed in a 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.	An IOL is placed in a 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.
Pre-loaded IOL	No	No
Material (Injector)	Titanium	Titanium
Material (cartridge)	Polypropylene	Polypropylene
Cartridge Coating	LubriMATRIX™	LubriMATRIX™
How Supplied (Reusable/Single Use)	Handpiece - Reusable Cartridge - Single Use, supplied sterile	Handpiece - Reusable Cartridge - Single Use, supplied sterile
Method of Sterilization	Handpiece - Autoclave Cartridge - Ethylene Oxide to SAL 10-6	Handpiece - Autoclave Cartridge - Ethylene Oxide to SAL 10-6

1.4 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.

Non-clinical performance testing included simulated surgical manipulation and recovery of properties including both pre- and post-injection evaluation of aged IOLs in accordance with ISO 11979-3:2012 in support of the proposed 1 year shelf-life. Specifically, mechanical dimensions and sagitta were verified following lens delivery and compared to the measurements performed prior to the lens delivery per ISO 11979-3:2012. Optical properties including overall surface and bulk homogeneity were tested pre- and post-lens injection per ISO 11979-2:2014.

Additionally, a particulate analysis was performed on aged product to demonstrate coating stability of the sterile insertion device coating following shelf-life aging.

Endothelial Cell Density Clinical Data

To evaluate whether the RxSight insertion device (with associated insertion methods) presents a significant risk to the corneal endothelium, post-operative endothelial cell density (ECD) data was collected in a prospective clinical study. This study compared the ECD changes following cataract surgery between eyes implanted with the RxLAL using the RxSight insertion device and eyes implanted with a commercially available monofocal control IOL and associated insertion device. The analysis presented in the 510(k) shows similar rates of ECD loss in eyes implanted with either device, supporting the safety of insertion of the LAL with the RxSight Insertion device.

Conclusion

The RxSight Insertion Device has the same intended use as the legally marketed predicate devices identified in this 510(k) premarket notification and other IOL injectors regulated under 21 CFR 886.4300. This device continues to meet all product design requirements and applicable standards and embodies technological characteristics similar to the predicate device. Performance data support the conclusion that the proposed RxSight Insertion Device is substantially equivalent to the predicate device.