June 10, 2026

℅ Maureen O'Connell
Executive Vice President, Clinical and Regulatory Affairs
RxSight, Inc.
100 Columbia, Aliso Viejo, CA 92656 USA

Re: K261174
Trade/Device Name: RxSight Insertion Devices (Model 63000/63001 and Model 63002)
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I, reserved
Product Code: MSS
Dated: May 19, 2026
Received: May 19, 2026

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

BENNETT N. WALKER -S

Digitally signed by BENNETT N. WALKER -S
Date: 2026.06.10 09:58:49 -04'00'

Bennett Walker, Ph.D.
Assistant 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261174

Please provide the device trade name(s).

RxSight® Insertion Device

Please provide your Indications for Use below.

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®, RxSight Light Adjustable Lens+(TM), and IOL models validated for use with this device in IOL approved labeling.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(K) SUMMARY
K261174

This 510(k) Summary 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 Executive Vice President, Clinical and Regulatory Affairs moconnell@rxsight.com Tel: (978) 207-1245
DATE SUMMARY PREPARED:	June 8, 2026
TRADE NAME:	RxSight Insertion Device
COMMON NAME:	Intraocular Lens (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 cleared in K231466 and K231838

Device Description

The RxSight Insertion Device (Model 63000/63001) is a two-part intraocular lens (IOL) injector device comprised of a re-usable handheld titanium Injector Handpiece, and a single use, non-preloaded disposable polypropylene Injector Cartridge intended to be used together to fold and insert the intraocular lenses into the eye through a small incision during cataract surgery.

The RxSight Insertion Device (Model 63002) is a sterile, single-use device used to fold and insert intraocular lenses (IOL) into the eye through a small incision during cataract surgery. The RxSight Insertion Device (Model 63002) consists of:

- A single-use, disposable, sterile IOL inserter with a non-pyrogenic cartridge
- A single-use, disposable, sterile haptic puller.

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®, RxSight Light Adjustable Lens+™, and IOL models validated for use with this device in IOL approved labeling.

Technological Characteristics Comparison

A comparison of the technological characteristics of the proposed and predicate devices is provided in the tables below.

Comparison of the RxSight Insertion Device (Model 63000/63001) to the Predicate Device

	RxSight Insertion Device (Model 63000/63001) Subject Device	**RxSight Insertion Device (Model 63000/63001) Predicate Device (K231466)**
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®, RxSight Light Adjustable Lens+™, 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 intended for the insertion of the RxSight Light Adjustable Lens®, RxSight Light Adjustable Lens+™, the Bausch & Lomb LI61A0 IOL and IOL models validated for use with this device in IOL approved labeling.
Operating Principle	An intraocular lens (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 intraocular lens (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 (resin mixture)	Polypropylene

	RxSight Insertion Device (Model 63000/63001) Subject Device	RxSight Insertion Device (Model 63000/63001) Predicate Device (K231466)
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}
Shelf-life (Cartridge)	18-month	12-month

Comparison of the RxSight Insertion Device (Model 63002) to the Predicate Device

	RxSight Insertion Device (Model 63002) Subject Device	RxSight Insertion Device (Model 63002) Predicate Device (K231838)
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®, RxSight Light Adjustable Lens+, and IOL models validated for use with this device in IOL approved labeling.	The RxSight® Insertion Device (Model 63002) 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 (Model 63002) is intended for the insertion of the RxSight Light Adjustable Lens®, RxSight Light Adjustable Lens+, and IOL models validated for use with this device in IOL approved labeling.
Operating Principle	An intraocular lens (IOL) is placed in a loading cartridge. Screw plunger advances the IOL through the cartridge which folds the IOL and advances it into the eye.	An intraocular lens (IOL) is placed in a loading cartridge. Screw plunger advances the IOL through the cartridge which folds the IOL and advances it into the eye.

	RxSight Insertion Device (Model 63002) Subject Device	RxSight Insertion Device (Model 63002) Predicate Device (K231838)
Pre-loaded IOL	No	No
Material (Injector)	Polycarbonate Polybutylene terephthalate polymer	Polycarbonate Polybutylene terephthalate polymer
Material (Cartridge)	Polypropylene (resin mixture)	Polypropylene
Cartridge Coating	LubriMATRIX™	LubriMATRIX™
How Supplied (Reusable/Single Use)	Sterile and Single use	Sterile and Single use
Method of Sterilization	Ethylene Oxide to SAL 10^{-6}	Ethylene Oxide to SAL 10^{-6}
Shelf-life	18-month	18-month

Summary of Performance Test Results

The descriptive characteristics are well-defined and adequate to ensure equivalence of the RxSight Insertion Devices (Model 63000/63001 and Model 63002) with the predicate devices. The subject devices and their predicates met the same requirements of non-clinical performance testing (simulated surgical manipulation and recovery of properties) including both pre- and post-injection evaluation of the intraocular lenses (IOLs) in accordance with ISO 11979-3:2012. Specifically, dimensions and sagitta were verified following lens delivery and compared to the measurements performed prior to the lens delivery per ISO 11979-3:2012. Additionally, recovery of optical properties and overall surface and bulk homogeneity were tested and met the requirements pre and post lens injection per ISO 11979-2:2014. Biocompatibility testing was performed per relevant parts of ISO 10993 standard series (i.e., ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-11, ISO 10993-12, and ISO 10993-23) and test results met the same acceptance criteria as the predicate devices.

Conclusion

The subject devices have the same intended use as the legally marketed predicate devices. Both the subject devices and the predicate devices have identical technological characteristics for lens insertion during cataract surgery. Both utilize a non-preloaded cartridge that is used to fold and position the lens on top of a handheld injector prior to lens delivery. Performance data is available which supports the substantial equivalence of the subject devices to the predicate devices.

The subject devices and their predicates met the same requirements of non-clinical performance testing (simulated surgical manipulation and recovery of properties) in accordance with ISO 11979-3:2012. Additionally, recovery of optical properties and overall surface and bulk homogeneity were tested and met the requirements pre and post lens injection per ISO 11979-2:2014. Biocompatibility testing was performed per relevant parts of ISO 10993 standard series (i.e., ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-11, ISO 10993-12, and ISO 10993-23) and test results met the same acceptance criteria as the predicate devices.

Therefore, the RxSight Insertion Device (Model 63000/63001 and Model 63002) with the proposed changes in cartridge material and shelf-life is substantially equivalent to the RxSight Insertion Devices that were cleared in K231466 and K231838.