August 15, 2023

RxSight, Inc.
Maureen OConnell
Senior Vice President, Clinical and Regulatory Affairs
100 Columbia
Aliso Viejo, California 92656

Re: K231838
Trade/Device Name: RxSight® Insertion Device (63002)
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular lens guide
Regulatory Class: Class I, reserved
Product Code: MSS
Dated: June 22, 2023
Received: June 22, 2023

Dear Ms. Maureen OConnell:

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,

Elvin Y. Ng -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K231838

Device Name

RxSight® Insertion Device (63002)

Indications for Use *(Describe)*

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.

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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# 510(k) SUMMARY
# RxSight® Insertion Device (Model 63002)

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


| | |
|---|---|
| **APPLICANT:** | RxSight, Inc.<br>100 Columbia<br>Aliso Viejo, CA 92656 |
| **CONTACT PERSON:** | Maureen O'Connell<br>Sr. Vice President Clinical and Regulatory Affairs<br>moconnell@rxsight.com<br>Tel: (978) 207-1245 |


| | |
|---|---|
| **DATE SUMMARY PREPARED:** | August 15, 2023 |
| **TRADE NAME:** | RxSight Insertion Device (Model 63002) |
| **COMMON NAME:** | IOL Injector |
| **CLASSIFICATION NAME:** | Intraocular Lens (IOL) Guide |
| **DEVICE CLASSIFICATION:** | Class I; 21 CFR 886.4300 |
| **PRODUCT CODE:** | MSS |
| **PREDICATE DEVICE(S):** | Primary: RxSight Insertion Device, K231466<br>Secondary: pioli IOL Delivery System, K172228 |

## 1.1 DEVICE DESCRIPTION

The RxSight Insertion Device (Model 63002) is a sterile, single-use device to be 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.

## 1.2 INDICATIONS FOR USE

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 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.

### 1.3 TECHNOLOGICAL CHARACTERISTICS COMPARISON

RxSight believes that the RxSight Insertion Device (Model 63002) described in this notification and for use under the conditions of the proposed labeling is substantially equivalent to legally marketed predicate devices that are Class I medical devices. The following table compares the RxSight Insertion Device (Model 63002) with the primary predicate device which is the RxSight Insertion Device (Model 63000/63001) cleared most recently in K231466 and the secondary predicate device, the AST Products pioli IOL Delivery System cleared in K172228.

**COMPARISON OF THE RXSIGHT INSERTION DEVICE (MODEL 63002) TO THE PREDICATE DEVICES**

| | **Proposed Device** | **Primary Predicate Device** | **Secondary Predicate Device** |
|---|---|---|---|
| | **RxSight Insertion Device (Model 63002)** | **RxSight Insertion Device (Model 63000/63001)** | **AST Products pioli IOL Delivery System** |
| **510(k) Number** | - | **K231466** | **K172228** |
| **Product Code** | MSS | MSS | MSS |
| **Intended Use** | Intraocular Lens Delivery | Intraocular Lens Delivery | Intraocular Lens Delivery |
| **Indications for Use** | 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. | 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 RxSight Light Adjustable Lens+, the Bausch & Lomb LI61A0 IOL and IOL models validated for use with this device in IOL approved labeling. | 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** | An 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 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. | Cartridge is back loaded into the injection system with a plunger that advances the IOL through the cartridge and into the eye |
| **Pre-loaded IOL** | No | No | No |
| **Material (Injector)** | Polycarbonate | Titanium | Polypropylene |

| | Proposed Device | Primary Predicate Device | Secondary Predicate Device |
|---|---|---|---|
| | **RxSight Insertion Device (Model 63002)** | **RxSight Insertion Device (Model 63000/63001)** | **AST Products pioli IOL Delivery System** |
| | Polybutylene terephthalate polymer | | |
| **Material (cartridge)** | Polypropylene | Polypropylene | Polypropylene |
| **Cartridge Coating** | LubriMATRIX™ | LubriMATRIX™ | LubriMATRIX™ |
| **How Supplied (Reusable/Single Use)** | Single Use, supplied sterile | Handpiece - Reusable Cartridge - Single Use, supplied sterile | Single Use, supplied sterile |
| **Method of Sterilization** | Ethylene Oxide to SAL $10^{-6}$ | Handpiece - Autoclave Cartridge - Ethylene Oxide to SAL $10^{-6}$ | 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 devices.

Non-clinical performance testing included simulated surgical manipulation and recovery of properties including both pre- and post-injection evaluation of the IOLs in accordance with ISO 11979-3:2012. 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. Additionally, optical properties and overall surface and bulk homogeneity were tested pre and post lens injection per ISO 11979-2:2014.

Conclusion

The RxSight Insertion Device (Model 63002) 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 meets all product design requirements and applicable standards and embodies technological characteristics similar to the predicate devices. Non-clinical data establish that the device is safe and effective in the delivery of the RxSight Light Adjustable Lens and Light Adjustable Lens+ and is shown to be substantially equivalent to the predicate devices.