September 10, 2020

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

Re: K201909
Trade/Device Name: RxSight Contact Lens
Regulation Number: 21 CFR 886.1385
Regulation Name: Polymethylmethacrylate (PMMA) Diagnostic Contact Lens
Regulatory Class: Class II
Product Code: HJK
Dated: July 8, 2020
Received: July 9, 2020

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. 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 Ng
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)* K201909

Device Name
RxSight Contact Lens

Indications for Use *(Describe)*
The RxSight Contact Lens is indicated for visualization and treatment in the anterior segment of the eye.

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 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:	September 4, 2020
TRADE NAME:	RxSight Contact Lens
COMMON NAME:	Diagnostic Contact Lens
CLASSIFICATION NAME:	Polymethylmethacrylate (PMMA) Diagnostic Contact Lens
DEVICE CLASSIFICATION:	Class II; 21 CFR 886.1385
PRODUCT CODE:	HJK
PREDICATE DEVICE:	Ocular Instruments 12.5 mm Peyman Wide Field YAG Laser Lens, K872136

DEVICE DESCRIPTION

The RxSight Contact Lens is a reusable diagnostic contact lens intended for intraocular visualization and therapy. The RxSight Contact Lens is used to maintain optical quality of the corneal surface and will provide lid stabilization to prevent blinking during therapeutic procedures that require magnification of the eye.

The RxSight Contact Lens is designed around the classic diagnostic contact lens with similar design including an optical element with a specific magnification to provide excellent visualization.

The optical component of the RxSight Contact Lens is made from polymethylmethacrylate (PMMA). The anodized aluminum cone houses the PMMA contact lens.

INDICATIONS FOR USE

The RxSight Contact Lens is indicated for visualization and treatment in the anterior segment of the eye.

TECHNOLOGICAL CHARACTERISTICS COMPARISON

The technical features of the RxSight Contact Lens are the same as the features of the predicate device described in the table below. A comparison of the technological characteristics of the proposed and predicate devices is provided in the table below.

	Proposed Device RxSight Contact Lens	**Ocular Instruments 12.5 mm Peyman Wide Field YAG Laser Lens (K872136)**
Product Code	HJK	HJK
Device Classification	21 CFR 886.1385	21 CFR 886.1385
Intended Use	Intended to aid in visualization and/or therapy in the anterior segment of the eye	Intended to aid in visualization and/or therapy in the anterior segment of the eye
Contact Material	PMMA	PMMA
Field of View	Wide angle	Wide Angle
Image Magnification	1.30x	1.40x
Laser Spot Magnification	0.766x	0.710x
Contact Diameter	15.0 mm	15.5 mm
Lens Height	16.5 mm	16.5 mm
How Supplied (Reusable/Single Use)	Single lens packaging, Non-sterile, Reusable	Single lens packaging, Non-sterile, Reusable

SUMMARY OF PERFORMANCE TEST RESULTS

Performance standards for contact lenses have not been issued. The descriptive characteristics of the RxSight Contact Lens are well-defined and adequate to ensure equivalence to the predicate device.

The following tests were successfully performed with the device components to establish substantial equivalence of the RxSight Contact Lens to the predicate device:

- Biocompatibility testing in accordance with ISO 10993-1 including Cytotoxicity (per ISO10993-5), Sensitization (per ISO10993-10), and Ocular Irritation (per ISO10993-10).
- Sterilization validation was performed to confirm that recommended sterilization parameters for this device achieved a Sterility Assurance Level of 10^{-6}, in accordance with ISO 10993-7.
- Finished product performance testing met all acceptance criteria.

SUBSTANTIAL EQUIVALENCE

The RxSight Contact Lens is substantially equivalent to the Ocular Instruments 12.5 mm Peyman Wide Field YAG Laser Lens cleared under K872136. These cleared devices are intended for use to enhance visualization and to aid in the treatment of the anterior segment of the eye. The predicate device is manufactured from the same materials, have the same technological characteristics and principles of operation as the RxSight Contact Lens. Any minor variation in specifications to the predicate devices do not impact safety or effectiveness of the lens during use.