December 14, 2021

Centricity Vision, Inc.
Neal Hartman
Vice President, Regulatory Affairs/Quality Assurance
1939 Palomar Oaks Way, Suite A
Carlsbad, CA 92011

Re: K210827
Trade/Device Name: ZEPTO Precision Capsulotomy System
Regulation Number: 21 CFR 886.4100
Regulation Name: Radiofrequency Electrosurgical Cautery Apparatus
Regulatory Class: Class II
Product Code: PUL
Dated: November 3, 2021
Received: November 5, 2021

Dear Neal Hartman:

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 titled "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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210827

Device Name
ZEPTO Precision Capsulotomy System

Indications for Use *(Describe)*
ZEPTO Precision Capsulotomy System is indicated for use in performing anterior capsulotomy during cataract surgery.

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.

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Centricity Vision

K210827 – 510(K) SUMMARY

Submitter Information

Company Name:	Centricity Vision, Inc.
Company Address:	1939 Palomar Oaks Way, Suite A Carlsbad, CA 92011
Company Phone:	(760) 456-5015
Company Facsimile:	(760) 579-6116
Contact Person:	Neal Hartman Vice President, Regulatory Affairs/Quality Assurance nhartman@centricityvision.com
Date:	November 22, 2021

Device Identification

Device Trade Name:	ZEPTO Precision Capsulotomy System
Common Name:	Capsulotomy Device
Classification Name(s):	Apparatus, Cutting, Radiofrequency, Electrosurgical, AC-Powered
Regulation(s):	886.4100
Device Class:	Class II
Product Code(s):	PUL
Advisory Panel:	Ophthalmic

Identification of Predicate Devices

The Subject Device is substantially equivalent to the following device:

Device Name	Classification Regulation	Product Code	510(K) Number	Clearance Date
ZEPTO	886.4100 - Apparatus, Cutting, Radiofrequency, Electrosurgical, AC-Powered	PUL	K170655	6/2/2017

Device Description

The Subject Device consists of a Power Console, Disposable Handpiece, and a disposable Fluid Isolator. The Disposable Handpiece's power cord connector is connected to the front panel of the Power Console to provide power for the capsulotomy procedure. The suction tubing from the Disposable Handpiece is connected to the Fluid Isolator. The Fluid Isolator is then connected to the Power Console's front panel to provide suction during the treatment to a suction cup containing the cutting element. The functional portion used for capsulotomy is the capsulotomy tip located at the distal end of the Disposable Handpiece, which consists of a circular, silicone suction cup, and circular cutting element. Energy pulses are delivered to the cutting element to create the capsulotomy.

Prior to conducting the capsulotomy, the Disposable Handpiece's suction line is primed Balanced Salt Solution (BSS).

The capsulotomy tip is elongate by sliding the finger slider distally, this allow the allows it to be easy inserted into the anterior chamber through the corneal incision. Once inserted into the anterior chamber the finger slider is pulled back to return the suction cup/cutting element to their original circular shapes. After centering the cutting element at the desired location on the anterior capsule, suction is initiated on the Power Console, which provides vacuum at the capsulotomy tip to properly seat the cutting element to anterior capsule.

Once suction is achieved, energy is initiated on the Power Console. A series of electrical pulses lasting a total of 4 milliseconds is delivered to the cutting element causing rapid phase transition of water molecules trapped between the bottom edge of the cutting element and the anterior capsule. The rapid volume expansion results in the capsule cutting action. Suction is then vented to atmosphere. The capsulotomy is nominally 5mm.

A nurse assistant will, upon command from the physician, introduce a small amount of BSS into the suction cup to allow for a gentle release of the suction cup from the capsule, and to allow the free-floating capsule button to stay behind in the anterior chamber for manual removal with forceps. This is done by advancing the fluid displacement syringe

forward. Upon completion of the capsulotomy, the capsulotomy tip is removed from the anterior chamber of the eye through the corneal incision.

The Disposable Handpiece with Fluid Isolator is packaged in a sterile barrier thermoform tray. The contents in the sterile barrier are sterile via Ethylene Oxide (EO) sterilization.

Indications for Use

ZEPTO Precision Capsulotomy System is indicated for use in performing anterior capsulotomy during cataract surgery.

Comparison of Technological Characteristics of Predicate and Subject Devices

Comparison Feature	Subject Device	Predicate Device
Device name	ZEPTO Precision Capsulotomy System	ZEPTO
Manufacturer	Centricity Vision, Inc	Centricity Vision, Inc. (Previously known as Mynosys Cellular Devices, Inc.)
Device classification	2	2
Indications for Use	ZEPTO Precision Capsulotomy System is indicated for use in performing anterior capsulotomy during cataract surgery.	Zepto is indicated for use in performing anterior capsulotomy during cataract surgery.
System components	• Power Console • Disposable Handpiece • Disposable Fluid Isolator	• Power Console • Disposable Handpiece • Disposable Fluid Isolator
Patient contact system component	Capsulotomy Tip of the Disposable Handpiece	Capsulotomy Tip of the Disposable Handpiece
Single-use	• Disposable Handpiece • Disposable Fluid Isolator	• Disposable Handpiece • Disposable Fluid Isolator
Sterile	• Disposable Handpiece • Disposable Fluid Isolator	Disposable Handpiece
Method of sterilization, SAL	Ethylene Oxide, SAL 10^{-6}	Ethylene Oxide, SAL 10^{-6}
Packaging, Sterile Barrier	Thermoform Tray/Tyvek Lidding Stock	Tyvek Pouch
System control component	Power Console	Power Console
Electrical	100-240 volts AC, 50-60Hz, 1.66 amps	100-240 volts AC, 50-60Hz, 1.66 amps
Energy Type	Rectified RF Pulsed – DC	Rectified RF Pulsed – DC
Induction of Tensile Stress	By Suction Pressure	By Suction Pressure
Control Method	• Front Panel • Footswitch (Wired or Wireless)	Front Panel
Cutting Element	Circular	Circular

Comparison Feature	Subject Device	Predicate Device
Device name	ZEPTO Precision Capsulotomy System	ZEPTO
Shape		
Capsulotomy Size	5.0mm (nominal)	5.0mm (nominal)

Summary of Testing Performed

A program of design verification and validation testing was performed that includes the following:

- Biocompatibility
- Sterility and EO Residual
- Packaging Integrity (i.e., Sterile Barrier)
- Transportation
- Electromagnetic Compatibility and Electrical Safety
- Stability/Shelf-Life
- Performance/Functionality/Safety
- Software
- Simulated Use (Human Factors Evaluation)

Results of the evaluations demonstrate that the Subject Device met the safety and performance requirements as it relates to its indication for use.

Conclusions Drawn from Nonclinical Evaluation

The results of the evaluation demonstrate that the Subject Device is substantially equivalent to the Predicate Devices as it pertains to the indications for use and device performance.