April 11, 2023

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

Re: K223763
Trade/Device Name: ZeptoLink IOL Positioning System
Regulation Number: 21 CFR 886.4100
Regulation Name: Radiofrequency Electrosurgical Cautery Apparatus
Regulatory Class: Class II
Product Code: PUL
Dated: March 10, 2023
Received: March 13, 2023

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 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 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)*
K223763

Device Name
ZeptoLink IOL Positioning System

Indications for Use *(Describe)*
The ZeptoLink IOL Positioning 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

K223763 – 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:	April 11, 2023

Device Identification

Device Trade Name:	ZeptoLink IOL Positioning 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 Precision Capsulotomy System	886.4100 - Apparatus, Cutting, Radiofrequency, Electrosurgical, AC-Powered	PUL	K210827	12/14/2021

Device Description

The Subject Device is basically Predicate, which is currently on the market, but integrated with OEM Ultrasonic Phacoemulsification (USP) system. The Subject Device and the USP are both required to complete the capsulotomy. The Subject Device includes the following system components:

- Power Console with Power Supply
- Reusable Pneumatic Connection, USP VIT-to-ZeptoLink
- Disposable Handpieces
- USP Support Mounts

The Power Console includes a LCD touchscreen display, which can rotate for viewing at different angles. The console is mounted to the side of the USP with customized support mounts design for various USPs. The console includes hardware and software, which the software establishes a safe state in the event of faults. The safe state is redundant electrical isolation components and pressure isolation. Low positive pressure irrigation is allowed in the safe state to ensure release from the lens capsule. This mimics USP system's safe state architecture.

No electricity is shared between the Power Console and USP. The console is connected to an electrical outlet via a separate 12V power adapter module "power brick". The Disposable Handpiece's power cord is connected to the console. Energy delivery to the handpiece's capsulotomy tip is solely provided through the console.

Priming the handpiece's suction line, the suction used to create apposition of the capsulotomy tip, and positive pressure irrigation used to release the capsulotomy tip after capsulotomy are all performed with the USP's fluidics (i.e., irrigation and aspiration). The handpiece suction line is connected to the irrigation/aspiration lines of the USP's pack. A 0.22-micron filter incorporated on the suction line is inserted into the pressure sensing module located on the console's front panel. The filter provides a sterile barrier between the suction path of the handpiece and the console.

> Initial priming of the suction line is conducted by pressing the USP continuous irrigation icon on the user interface, or by pressing the fill functions icon in the USPs vitrectomy state. Should additional priming be required, the vitrectomy fill icon can be pressed more than once. If the suction line requires additional priming just prior to surgery, the surgeon can accomplish this by pressing the USP's footswitch to position one (1) to generate irrigation.
>
> The surgeon initiates suction by pressing the USP's footswitch to position two (2), which triggers the console to pinch off the irrigation line. Suction is maintained with continued pressure to the footswitch. The delivery of energy will not be authorized until a threshold vacuum pressure for a specified duration has been achieved. *Note*: *To stop suction, the surgeon simply releases pressure from the footswitch.*
>
> To release the capsulotomy tip after capsulotomy, the Surgeon releases pressure from the foot pedal. The console will release "un-pinch" the irrigation line after energy delivery.

There are a couple of ways to initiate energy delivery. The first method is to press the associated icon on the console's touch screen, which the sterile nurse will perform with verbal communication from the surgeon. The second method is through the USP's footswitch, which sends a signal through the vitrectomy port to the console, via the reusable pneumatic connection. The pneumatic pulse signal is recognized by the console and initiates energy delivery. The surgeon controls energy delivery with the second method. In both methods, energy delivery cannot occur without the suction parameters being met and the energy being unlocked, either manually by depressing the energy unlock icon on the console.

The Disposable Handpiece part of the Subject Device is identical to the Predicate with the exception of extending the suction line to incorporate the irrigation/ aspiration connections to the USP's disposable pack and 0.22-micron filter. The functional portion that executes that capsulotomy is the capsulotomy tip located at the distal end of the 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. This is identical to the Predicate.

Other than the above-mentioned procedural activities, the capsulotomy procedure is identical to the Predicate.The capsulotomy tip is elongate by sliding the finger slider distally, this allow 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, which the capsulotomy tip will applanate, seating the cutting element to anterior capsule.

Once suction is achieved, energy is initiated. 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. Depending on which handpiece configuration is used the capsulotomy size is nominally 5.1 or 5.4mm.

The surgeon will remove the capsulotomy tip from the anterior chamber through the corneal incision when it releases from the capsule. The capsule button will either come out when the capsulotomy tip is removed or be free-floating in the chamber where manual removal with forceps is required.

The Disposable Handpiece and the sterile drape for the Power Console display are packaged in a sterile barrier thermoform tray with Tyvek lid. Ten (10) packaged devices are inserted into an inner carton with the IFU then inserted into a shipper box. The contents in the sterile barrier are sterile via Ethylene Oxide (EO) sterilization.

The Power Console is packaged into an ESD protective bag and foam protectors are positioned of both side of the console then inserted into a shipper box. The power supply, power cord, and user manual are also provided in the shipper.

Reusable pneumatic connection and USP support mounts are be packaged separately.

Indications for Use

ZeptoLink IOL Positioning System is indicated for use in performing anterior capsulotomy during cataract surgery.

Comparison of Technological Characteristics with Predicate and Reference Devices

Comparison Feature	Subject Device	Predicate Device	Differences
Device name	ZeptoLink IOL Positioning System	ZEPTO Precision Capsulotomy System	N/A
Manufacturer	Centricity Vision, Inc	Centricity Vision, Inc	None
Device classification	2	2	None
Product Code	PUL	PUL	None
Indications for Use	ZeptoLink IOL Positioning System is indicated for use in performing anterior capsulotomy during cataract surgery.	ZEPTO Precision Capsulotomy System is indicated for use in performing anterior capsulotomy during cataract surgery.	None
System components	• Power Console • Disposable Handpiece • Pneumatic Communication Connection, USP Vitrectomy Port-to-Power Console	• Power Console • Disposable Handpiece • Disposable Fluid Isolator	The Subject Device requires a communication line between the console and the USP in order to allow the surgeon to execute capsulotomy energy from the USP footswitch. The sterile technician can only execute capsulotomy energy from the console with the Predicate. *Note: Execution of capsulotomy energy can also be conduct at the console display with the Subject Device.* The Subject Device does not require a fluid isolator because liquid isolation is conducted within console's suction sensor.
Patient contact system component	Capsulotomy Tip of the Disposable Handpiece	Capsulotomy Tip of the Disposable Handpiece	None
Single-use	• Disposable Handpiece	• Disposable Handpiece • Disposable Fluid Isolator	None, disposable system components are not reusable
Sterile	• Disposable Handpiece	• Disposable Handpiece • Disposable Fluid Isolator	None, disposable system components are terminally sterilized.
Method of sterilization, SAL	Ethylene Oxide, SAL 10^{-6}	Ethylene Oxide, SAL 10^{-6}	None
Packaging, Sterile Barrier	Thermoform Tray/Tyvek Lidding Stock	Thermoform Tray/Tyvek Lidding Stock	None
System control component	Power Console	Power Console	Both the Subject Device and Predicate control the execution of capsulotomy energy the same,

Comparison Feature	Subject Device	Predicate Device	Differences
Device name	ZeptoLink IOL Positioning System	ZEPTO Precision Capsulotomy System	N/A
			however they control suction differently. The Predicate suction sources is within the power console and controls pressure through internal software and electric controlled pressure regulator. The Subject Device uses the functionality of the USP for suction and monitors the pressure output through suction sensor in the power console via disposable handpiece's suction line. If high suction threshold is reached, the power console will occlude the disposable handpiece's suction line, via a pinch valve, to prevent excessive suction at the anterior capsule.
Electrical	100-240 volts AC, 50-60Hz, 1.66 amps	100-240 volts AC, 50-60Hz, 1.66 amps	None
Energy Type	Rectified RF Pulsed – DC	Rectified RF Pulsed – DC	None
Induction of Tensile Stress	By Suction Pressure	By Suction Pressure	None
User Interface	• Touchscreen Display (Power Console • Footswitch (USP)	• Front Panel (Power Console) • Footswitch (Power Console)	The Predicate can initiate suction and execute capsulotomy energy from the front panel of the power control. Optional, a footswitch accessory can be connected to the power console and these functions can be controlled through the footswitch. The Subject Device required energy to be unlock, when acceptable suction has been achieved, on the power console's touchscreen display in order to execute capsulotomy energy. Execution of capsulotomy energy is then performed on the touchscreen display. Initiating and maintaining suction, optional executing capsulotomy energy, and aiding with release of the disposable handpiece's capsulotomy tip from the anterior capsule is conducted through the USP footswitch.
Cutting Element Shape	Circular	Circular	None
Capsulotomy Diameter (Nominal)	5.0mm or 5.4mm	5.0mm or 5.4mm	None, there is two (2) handpiece configurations for the Subject Device and Predicate. Each configuration produces a different nominal capsulotomy diameter.

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)
- LAL Endotoxin Testing
- 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.