November 14, 2025

This AG
Anne-Marie Ripley
Clinical & Regulatory Affairs Consultant
Regulatory Pathways Group, Inc.
440 N. Barranca Ave., #2471
Covina, CA 91723

Re: K250501
Trade/Device Name: System Sophi
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: HQC, HQE
Dated: October 17, 2025
Received: October 17, 2025

Dear Anne-Marie Ripley:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

CLAUDINE H. KRAWCZYK -S

Claudine Krawczyk
Assistant Director
DHT1A: Division of Ophthalmic Devices
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Respiratory, ENT, and Dental Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250501

Device Name

System Sophi

Indications for Use *(Describe)*

The System Sophi is an integrated phacoemulsification lens removal device designed for use in intraocular ophthalmic surgery in the anterior chamber. System Sophi is intended for liquid irrigation and aspiration, lens fragmentation and ultrasonic phacoemulsification, anterior vitrectomy, and bipolar diathermy (high frequency surgical equipment).

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

1 Submission Sponsor

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2 Official Correspondent

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Phone: 661-645-8546

3 Date Prepared

November 4, 2025

4 Device Identification

Trade/Proprietary Name:	System Sophi
Classification Name:	Phacofragmentation system
Regulation Number(s):	886.4670
Product Code(s):	HQC, HQE
Class:	2
Classification Panel:	Ophthalmic

5 Legally Marketed Predicate Device

Device name:	EVA NEXUS Ophthalmic Surgical System
510(k) number:	K213467
Manufacturer:	D.O.R.C. Dutch Ophthalmic Research Center (International) B.V

6 Predicate Device Description

The EVA NEXUS Ophthalmic surgical system is used for both anterior segment (i.e. phacoemulsification and removal of cataracts) and posterior segment (i.e. vitreoretinal) ophthalmic surgery, including subretinal microinjection of gaseous or liquids, and laser surgery.

7 Indication for Use Statement

The System Sophi is an integrated phacoemulsification lens removal device designed for use in intraocular ophthalmic surgery in the anterior chamber. System Sophi is intended for liquid irrigation and aspiration, lens fragmentation and ultrasonic phacoemulsification, anterior vitrectomy, and bipolar diathermy (high frequency surgical equipment)

8 Device Description

The System Sophi is an integrated phacoemulsification lens removal device designed for use in intraocular ophthalmic surgery in the anterior chamber. System Sophi is intended for lens fragmentation and ultrasonic phacoemulsification, liquid irrigation and aspiration, anterior vitrectomy, and bipolar diathermy (high frequency surgical equipment).

A cassette is the interface between the System Sophi device and the surgical handpiece. It is used to regulate the balanced saline solution (BSS) irrigating fluid to the handpiece, to aspirate lens fragments and liquids from the handpiece, to monitor irrigation and aspiration flow and pressure and deposition of lens fragments and fluid into the waste bag for disposal. The cassette ports and tube connectors are coded to ensure proper connections at any time.

The system is controlled with a foot pedal (surgeon) and a graphical user interface (assistant).

System Sophi is powered by mains voltage (AC-powered) or through a battery.

Only company-validated and recommended disposable sterile equipment and designated instruments and hand pieces are allowed.

The Sophi system is offered in three configurations: Sophi Premium, Sophi Eco and Sophi A, differing in the included options and accessories.

9 Substantial Equivalence Discussion

The following table compares the System Sophi to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

10 Comparison of Characteristics

Attribute	Predicate Device EVA NEXUS Ophthalmic Surgical System	Subject Device System Sophi	Device Comparison
Manufacturer	D.O.R.C. Dutch Ophthalmic Research Center	This AG	N/A
US Premarket Notification	K213467	Pending	N/A
Product Codes	HQC HQE HQF FMF	HQC HQE	Different, differences not affecting safety or performance
Regulation Number	§886.4670 Phacofragmentation System §886.4150 Vitreous aspiration and cutting instrument §886.4390 Ophthalmic Laser §886.5860 Piston Syringe	§886.4670 Phacofragmentation System §886.4150 Vitreous aspiration and cutting instrument	As above
Device Class	II	II	Same
Intended Use	Ophthalmic surgery	Ophthalmic surgery	Same

Attribute	Predicate Device EVA NEXUS Ophthalmic Surgical System	Subject Device System Sophi	Device Comparison
Indications for Use	The EVA NEXUS Ophthalmic surgical system is indicated for both anterior segment (i.e. phacoemulsification and removal of cataracts) and posterior segment (i.e. vitreoretinal) ophthalmic surgery, including subretinal microinjection of gaseous or liquids.	The System Sophi is an integrated phacoemulsification lens removal device designed for use in intraocular ophthalmic surgery in the anterior chamber. System Sophi is intended for liquid irrigation and aspiration, lens fragmentation and ultrasonic phacoemulsification, anterior vitrectomy, and bipolar diathermy (high frequency surgical equipment).	Similar, differences not affecting safety or performance
	In addition, the optional laser is indicated for the following: Condition — Treatment Diabetic Retinopathy Proliferative Diabetic Retinopathy — Panretinal Photocoagulation Clinically Significant Macular Edema — Focal or Grid Laser Retinal Tear and Detachments — Laser Retinopathy Lattice Degeneration — Retinal Photocoagulation Sub-retinal (choroidal) Neovascularization — Focal Laser Retinal Vascular Occlusion Neovascularization secondary to Brand or Central retinal vein occlusion — Scatter Laser Photocoagulation Chronic macular edema secondary to Branch or Central retinal vein occlusion — Focal or Grid Laser Glaucoma Primary Open-angle Closed Angle — Trabeculoplast Iridotomy or Iridoplasty	N/A	The Subject Device does not include a laser
Design functions	- Phacoemulsification - Vitrectomy - Diathermy - Irrigation / Aspiration - Illumination - Fluid/Air exchange - Viscous fluid control (injection, extraction, Micro Injection) - Laser - Visualization (Digital overlay)	- Phacoemulsification - Vitrectomy - Diathermy - Irrigation / Aspiration - Fluid/Air exchange	Different, differences not affecting safety or performance
Device Components	Console, footswitch, power cable, accessories for different purposes including phacoemulsification, vitrectomy, illumination, Inspiration/Aspiration, diathermy, and laser. Procedure packs.	Console, footswitch, power cable, accessories for different purposes including phacoemulsification, vitrectomy, Inspiration/Aspiration, diathermy. Procedure packs.	Similar, differences not affecting safety or performance

Attribute	Predicate Device EVA NEXUS Ophthalmic Surgical System	Subject Device System Sophi	Device Comparison
Accessories	Console Plastic dust cover and protective flight case or carton Disposable - Primary EO sterilization package and protective box Reusable - Protective packaging	Console Plastic dust cover and protective flight case or carton Disposable - Primary EO sterilization package and protective box Protective packaging	Same
Software Operating System	Windows embedded OS	Linux	Different, differences not affecting safety or performance
Power Source	AC: 110 – 240 V, 50Hz/60Hz	AC: 110 – 240 V, 50Hz/60Hz	Same
Electrical Safety, Electromagnetic Compatibility standards	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	Same
User Interfaces	The user selects settings for the various functions on the Graphical User Interface by the touch the screen. The user starts, stops, and regulates the various functions with the foot switch.	The user selects settings for the various functions on the Graphical User Interface by the touch screen. The user starts, stops, and regulates the various functions with the foot switch.	Same
Irrigation (Infusion) modes	Modes: Fixed/AIC/SMART IOP	Modes: Active IOP or gravitation	Similar, differences not affecting safety or performance
Aspiration modes	Flow mode or vacuum mode	Flow mode or vacuum mode	Same
Cassette/ Cartridge and Tubing Sets	The cartridge consists of a collection bag to collect aspiration fluids, tubing for irrigation and aspiration and the tubing for the administration set. Fluid circulation is achieved by the interaction of the membrane and the pump pistons.	The cassette/cartridge consists of a collection bag to collect aspiration fluids, tubing for irrigation and aspiration. Fluid circulation is achieved by the interaction of the peristaltic or venturi pump.	Similar, differences not affecting safety or performance
Console screen	Glass Color display Touchscreen (19“) with programmable Graphical User Interface	Glass Color display Touchscreen (19“ & 15“) with programmable Graphical User Interface	Similar, differences not affecting safety or performance .
Multi-function footswitch	Multi-function footswitch with a dual-linear pedal and programmable function buttons to control all functions including laser. Wired and Wireless connection to the console. Battery-operated with wall charger on Device and back-up power/connection cable.	Multi-function footswitch with a dual-linear pedal and programmable function buttons to control all functions. Wired and Wireless connection to the console. Battery-operated with back-up power/connection cable.	Same
Phaco Principle of operation	The Phaco Module can be used for Phaco emulsification and fragmentation. The module provides ultrasound power with continuous autotuning. The module drives a connected Phaco handpiece. The handpiece contains piezo-electric elements which transforms the electrical drive energy into an ultrasonic output at the distal end of the handpiece needle.	The Phaco Module can be used for Phaco emulsification and fragmentation. The module provides ultrasound power with continuous autotuning. The module drives a connected Phaco handpiece. The handpiece contains piezo-electric elements which transforms the electrical drive energy into an ultrasonic output at the distal end of the handpiece needle.	Same

Attribute	Predicate Device EVA NEXUS Ophthalmic Surgical System	Subject Device System Sophi	Device Comparison
Phaco frequency	40kHz Auto-tuning	40kHz Auto-tuning	Same
Vitrectomy	TDC Two Dimensional Cutter	Bi-Blade Vitrectomy Cutter by MID Labs , USA	The Bi-Blade Vitrectomy Cutter is a 3rd-Party market-cleared accessory (K153168)
Vitrectomy Power source for cutter activation	Pneumatic pressure pulse	Pneumatic pressure pulse	Same
Diathermy	Various forceps and pencils Accessories to the predicate device	Various forceps and pencils by Kirwan Surgical Products, USA	The Diathermy items are 3rd-Party market-cleared accessories
Diathermy Principle of operation	Provides coagulation for anterior and posterior eye-segment surgery.	The Diathermy Module provides coagulation for anterior eye-segment surgery.	Same
Diathermy Type	Bipolar Coagulation	Bipolar Coagulation	Same
Diathermy Driving Frequency	1 MHz (±10%)	0.5 MHz (±10%)	Similar, differences not affecting safety or performance.
Electrical Safety Testing	passed	passed	Same
EMC/EMD Testing	passed	passed	Same
Complies with ISO 10993-1	passed	passed	Same

11 Non-Clinical Performance Data

To demonstrate safety and effectiveness of System Sophi and to show substantial equivalence to the predicate device, This AG completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. The System Sophi passed the following testing in accordance with internal requirements, FDA guidance, and international standards as described below, supporting its safety and effectiveness, and its substantial equivalence to the predicate device:

- **Electrical Safety Testing** was performed to demonstrate the Sophi System meets the following standard:
  - IEC 60601-1:2020, “Medical electrical equipment – Part 1: General requirements for safety 1: collateral standard: Safety Requirements for Medical Electrical Systems”
- **Electromagnetic Compatibility (EMC) Testing** was conducted to demonstrate that the System Sophi meets the following standards:
  - IEC 60601-1-2:2020, “Medical electrical equipment – Part 1-2: General requirements for safety and essential performance – Collateral Standard: Electromagnetic compatibility – Requirements and tests.”

    - Additional EMC testing for common electromagnetic emitters was conducted in accordance with FDA guidance, "Electromagnetic Compatibility (EMC) of Medical Devices"
    - Wireless coexistence testing was conducted to demonstrate compliance with IEEE ANSI USEMCSC C63.27-2021, "American National Standard for Evaluation of Wireless Coexistence"
- Testing was performed to demonstrate the Sophi System meets the requirements for lens removal devices, vitrectomy devices, and high frequency surgical equipment per the following standards:
    - IEC 80601-2-58, "Medical electrical equipment - Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery"
    - Basic safety and essential performance of high frequency surgical equipment was conducted per IEC 60601-2-2:2017, "Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories"
- **Biocompatibility:** The biocompatibility profile of the direct and indirect tissue contacting components of the device were assessed for cytotoxicity, sensitization, Irritation, acute systemic toxicity, and material-mediated pyrogenicity as recommended in FDA's 2020 Biocompatibility Guidance, "Biocompatibility Testing of Medical Devices - Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program: Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff" and relevant parts of ISO 10993 Biological Evaluation of Medical Devices standard series.
- **Software verification and validation testing:** The System Sophi software was developed and verified in accordance with FDA's 2023 guidance, "Content of Premarket Submissions for Device Software Functions." The software is classified as an Enhanced Document level per FDA's guidance document.
- **Cybersecurity testing** was performed in accordance with FDA guidance, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions."
- **Sterilization validation** was performed per ISO 11135:2014 to demonstrate that the sterilization process for the sterile accessories reliably sterilizes the product with a sterility assurance level (SAL) of 10^{-6}. EO/ECH residuals testing was performed per ISO 10993-7:2008 to demonstrate the sterile accessories maintain acceptable residuals levels post-sterilization. Endotoxin testing (LAL) was performed per ANSI/AAMI ST72:2019 to demonstrate that the sterile accessories maintain acceptable endotoxin levels.
- **Packaging validation/shelf life studies** were performed to validate the packaging and claimed shelf life for the sterile accessories. Transit conditioning was conducted per ISO 11607-1, ASTM D7386 and ASTM D4169. Aging studies were conducted per ASTM F1980. Whole packaging integrity, seal integrity, visual inspection, and label adhesion/legibility tests were performed.
- **Sterilization validation** was performed per ISO 17665-1:2006 to validate the sterilization instructions of the reusable handpiece.

12 Clinical Performance Data

No clinical data was necessary to determine the substantial equivalence of this device.

13 Statement of Substantial Equivalence

The System Sophi has the same intended use as the predicate device and similar technological characteristics. The differences in technological characteristics do not raise new or different questions of safety and effectiveness. Based on the results of the risk assessment and all applicable testing, the System Sophi is determined to perform as intended during normal anticipated usage and is at least as safe, as effective, and performs as well as or better than the legally marketed predicate device and therefore can be determined to be substantially equivalent to the predicate device.