May 15, 2026

Bausch and Lomb
Matthew Harrison
Senior Regulatory Affairs Specialist
3365 Tree Ct. Industrial Blvd.
Saint Louis, Missouri 63122

Re: K261264

Trade/Device Name: Stellaris Elite™ vision enhancement system;
Posterior and Combined Procedure Pack(s): 23 ga. Posterior Elite™ Pack (SE5423); 23 ga. Bi-Blade™ Vitreous Cutter Posterior Stellaris Elite™ Pack (SE5423B); 25 ga. Posterior Elite™ Pack (SE5425); 25 ga. Bi-Blade™ Vitreous Cutter Posterior Stellaris Elite™ Pack (SE5425B); 27 ga. Bi-Blade™ Vitreous Cutter Posterior Stellaris Elite™ Pack (SE5427B); 23 ga. Bi-Blade™+ Vitreous Cutter Posterior Stellaris Elite™ Pack (SE5423BB+); 25 ga. Bi-Blade™+ Vitreous Cutter Posterior Stellaris Elite™Pack (SE5425BB+); 27 ga. Bi-Blade™+ Vitreous Cutter Posterior Stellaris Elite™ Pack (SE5427BB+); TSV 23 ga. Posterior Vitrectomy Pack with AFI (BL5423X); TSV 25 ga. Posterior Vitrectomy Pack with AFI (BL5425X); 23 ga. Combined Elite™ Pack (SE5523); 23 ga. Bi-Blade™ Vitreous Cutter Combined Stellaris Elite™ Pack (SE5523B); 25 ga. Combined Elite™ Pack (SE5525); 25 ga. Bi-Blade™ Vitreous Cutter Combined Stellaris Elite™ Pack (SE5525B); 27 ga. Bi-Blade™ Vitreous Cutter Combined Stellaris Elite™ Pack (SE5527B); 23 ga. Bi-Blade™+ Vitreous Cutter Combined Stellaris Elite™ Pack (SE5523BB+); 25 ga. Bi-Blade™+ Vitreous Cutter Combined Stellaris Elite™ Pack (SE5525BB+); 27 ga. Bi-Blade™+ Vitreous Cutter Combined Stellaris Elite™ Pack (SE5527BB+); TSV 23 ga. Combined Vitrectomy Pack with AFI (BL5523X); TSV 25 ga. Combined Vitrectomy Pack with AFI (BL5525X);
Light Pipe(s): 23 ga. Mid-Field Light Pipe w/ESA (SE23MV); 25 ga. Mid-Field Light Pipe w/ESA (SE25MV); 27 ga. Mid-Field Light Pipe w/ESA (SE27MV); 23 ga. Wide-Field Light Pipe w/ESA (SE23WV); 25 ga. Wide-Field Light Pipe w/ESA (SE25WV); 27 ga. Wide-Field Light Pipe w/ESA (SE27WV); 23 ga. Wide-Field Light Pipe w/ESA (BL23WV); 25 ga. Wide-Field Light Pipe w/ESA (BL25WV)

Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: HQC, HQE, MPA
Dated: April 15, 2026
Received: April 16, 2026

Dear Matthew Harrison:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261264	?

Please provide the device trade name(s). ?

Stellaris Elite™ vision enhancement system;

Posterior and Combined Procedure Pack(s):
23 ga. Posterior Elite™ Pack (SE5423);
23 ga. Bi-Blade™ Vitreous Cutter Posterior Stellaris Elite™ Pack (SE5423B);
25 ga. Posterior Elite™ Pack (SE5425);
25 ga. Bi-Blade™ Vitreous Cutter Posterior Stellaris Elite™ Pack (SE5425B);
27 ga. Bi-Blade™ Vitreous Cutter Posterior Stellaris Elite™ Pack (SE5427B);
23 ga. Bi-Blade™+ Vitreous Cutter Posterior Stellaris Elite™ Pack (SE5423BB+);
25 ga. Bi-Blade™+ Vitreous Cutter Posterior Stellaris Elite™Pack (SE5425BB+);
27 ga. Bi-Blade™+ Vitreous Cutter Posterior Stellaris Elite™ Pack (SE5427BB+);
TSV 23 ga. Posterior Vitrectomy Pack with AFI (BL5423X);
TSV 25 ga. Posterior Vitrectomy Pack with AFI (BL5425X);
23 ga. Combined Elite™ Pack (SE5523);
23 ga. Bi-Blade™ Vitreous Cutter Combined Stellaris Elite™ Pack (SE5523B);
25 ga. Combined Elite™ Pack (SE5525);
25 ga. Bi-Blade™ Vitreous Cutter Combined Stellaris Elite™ Pack (SE5525B);
27 ga. Bi-Blade™ Vitreous Cutter Combined Stellaris Elite™ Pack (SE5527B);
23 ga. Bi-Blade™+ Vitreous Cutter Combined Stellaris Elite™ Pack (SE5523BB+);
25 ga. Bi-Blade™+ Vitreous Cutter Combined Stellaris Elite™ Pack (SE5525BB+);
27 ga. Bi-Blade™+ Vitreous Cutter Combined Stellaris Elite™ Pack (SE5527BB+);
TSV 23 ga. Combined Vitrectomy Pack with AFI (BL5523X);
TSV 25 ga. Combined Vitrectomy Pack with AFI (BL5525X);

Light Pipe(s):
23 ga. Mid-Field Light Pipe w/ESA (SE23MV);
25 ga. Mid-Field Light Pipe w/ESA (SE25MV);
27 ga. Mid-Field Light Pipe w/ESA (SE27MV);
23 ga. Wide-Field Light Pipe w/ESA (SE23WV);
25 ga. Wide-Field Light Pipe w/ESA (SE25WV);
27 ga. Wide-Field Light Pipe w/ESA (SE27WV);
23 ga. Wide-Field Light Pipe w/ESA (BL23WV);
25 ga. Wide-Field Light Pipe w/ESA (BL25WV)

Please provide your Indications for Use below. ?

Posterior and Combined Procedure Pack(s):

The Bausch + Lomb Stellaris Elite™ Vision Enhancement System is intended for the emulsification and removal of cataracts, anterior and posterior segment vitrectomy. The system is designed for use in both anterior and posterior segment surgeries. It provides capabilities for phacoemulsification, coaxial and bimanual irrigation/aspiration, bipolar coagulation, vitrectomy, viscous fluid injection/removal and air/fluid exchange operations. The Stellaris Elite™ Vision Enhancement System configured with the laser module is additionally intended for retinal photocoagulation and laser trabeculoplasty.

The Bausch + Lomb posterior and combined procedure packs are intended for use with the Bausch + Lomb

Stellaris Vision Enhancement Systems which are intended for the emulsification and removal of cataracts, anterior and posterior segment vitrectomy. They provide capabilities for phacoemulsification, coaxial and bimanual irrigation/aspiration, vitrectomy, and air/fluid exchange operations.

Light Pipe(s):
The Bausch + Lomb Stellaris Elite™ Vision Enhancement System is intended for the emulsification and removal of cataracts, anterior and posterior segment vitrectomy. The system is designed for use in both anterior and posterior segment surgeries. It provides capabilities for phacoemulsification, coaxial and bimanual irrigation/aspiration, bipolar coagulation, vitrectomy, viscous fluid injection/removal and air/fluid exchange operations. The Stellaris Elite™ Vision Enhancement System configured with the laser module is additionally intended for retinal photocoagulation and laser trabeculoplasty.

The Bausch + Lomb Light Pipes are intended for use with the Bausch + Lomb Stellaris Vision Enhancement Systems for use during anterior and posterior segment surgeries.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☐ Adults (22 years old and greater)	?

510(k) Summary

1 General Information

Submitter:
Bausch and Lomb Inc.
3365 Tree Court Industrial Blvd.
Saint Louis, MO 63122
General Telephone: 636-226-3017

Contact Person:
Matt Harrison
3365 Tree Court Industrial Blvd.
Saint Louis, MO 63122
(636) 200-8807
Matt.Harrison@Bausch.com

Preparation Date: May 15, 2026

2 Names

Device Name: Stellaris Elite™ vision enhancement system

Stellaris Elite™ Posterior and Combined Procedure Packs

- 23 ga. Posterior Elite™ Pack (SE5423)
- 23 ga. Bi-Blade™ Vitreous Cutter Posterior Stellaris Elite™ Pack (SE5423B)
- 25 ga. Posterior Elite™ Pack (SE5425)
- 25 ga. Bi-Blade™ Vitreous Cutter Posterior Stellaris Elite™ Pack (SE5425B)
- 27 ga. Bi-Blade™ Vitreous Cutter Posterior Stellaris Elite™ Pack (SE5427B)
- 23 ga. Bi-Blade™+ Vitreous Cutter Posterior Stellaris Elite™ Pack (SE5423BB+)
- 25 ga. Bi-Blade™+ Vitreous Cutter Posterior Stellaris Elite™ Pack (SE5425BB+)
- 27 ga. Bi-Blade™+ Vitreous Cutter Posterior Stellaris Elite™ Pack (SE5427BB+)
- 23 ga. Combined Elite™ Pack (SE5523)
- 23 ga. Bi-Blade™ Vitreous Cutter Combined Stellaris Elite™ Pack (SE5523B)
- 25 ga. Combined Elite™ Pack (SE5525)
- 25 ga. Bi-Blade™ Vitreous Cutter Combined Stellaris Elite™ Pack (SE5525B)
- 27 ga. Bi-Blade™ Vitreous Cutter Combined Stellaris Elite™ Pack (SE5527B)
- 23 ga. Bi-Blade™+ Vitreous Cutter Combined Stellaris Elite™ Pack (SE5523BB+)
- 25 ga. Bi-Blade™+ Vitreous Cutter Combined Stellaris Elite™ Pack (SE5525BB+)
- 27 ga. Bi-Blade™+ Vitreous Cutter Combined Stellaris Elite™ Pack (SE5527BB+)

Stellaris PC Posterior and Combined Procedure Packs

- TSV 23 ga. Posterior Vitrectomy Pack with AFI (BL5423X)
- TSV 25 ga. Posterior Vitrectomy Pack with AFI (BL5425X)
- TSV 23 ga. Combined Vitrectomy Pack with AFI (BL5523X)
- TSV 25 ga. Combined Vitrectomy Pack with AFI (BL5525X)

Light Pipes

- 23 ga. Mid-Field Light Pipe w/ESA (SE23MV)
- 25 ga. Mid-Field Light Pipe w/ESA (SE25MV)
- 27 ga. Mid-Field Light Pipe w/ESA (SE27MV)
- 23 ga. Wide-Field Light Pipe w/ESA (SE23WV)
- 25 ga. Wide-Field Light Pipe w/ESA (SE25WV)
- 27 ga. Wide-Field Light Pipe w/ESA (SE27WV)
- 23 ga. Wide-Field Light Pipe w/ESA (BL23WV)
- 25 ga. Wide-Field Light Pipe w/ESA (BL25WV)

Classification Names: Phacofragmentation Unit, Vitreous Aspiration and Cutting Instrument
Common Name: Ophthalmic surgical system for cataract and vitreo-retinal surgery
CFR References: 21 CFR Part 886.4670 - Phacofragmentation System (HQC)

(Product Codes) 21 CFR Part 886.4150 - Vitreous Aspiration and Cutting Instrument (HQE)
21 CFR Part 876.1500 - Endoscope and Accessories (MPA)

3 Predicate Devices

K162342 – Stellaris Elite™ vision enhancement system, Bausch + Lomb

4 Reference Devices

K252052 – Stellaris Elite™ vision enhancement system with Bi-Blade™+, Bausch + Lomb

5 Product Description

The Bausch + Lomb Stellaris Elite™ vision enhancement system is comprised of an integrated ophthalmic microsurgical system designed for use in anterior and posterior segment surgery including phacofragmentation, vitreous aspirating, cutting, and endoillumination. Additionally, the Stellaris Elite™ vision enhancement system may be configured with a laser module intended for retinal photocoagulation and laser trabeculoplasty.

A selection of disposable single-use procedure packs is available for use with the system. These packs contain the necessary tubing to facilitate delivery and removal of air and fluids to and from the patient as well as a selection of components (cannulas, cutters, probes, drapes, etc.) that facilitate the surgical procedure. The items are arranged for physician convenience and may be presented as a group intended to support all the needs of a procedure or packaged singularly to allow the physician greatest flexibility.

With this 510(k), Bausch + Lomb is introducing gamma-sterilized Posterior and Combined procedure packs and EO-sterilized Light Pipe and ESA pouches for use with Bausch + Lomb Stellaris Elite™ vision enhancement systems.

6 Indications for Use

Posterior and Combined Procedure Packs

The Bausch + Lomb Stellaris Elite™ Vision Enhancement System is intended for the emulsification and removal of cataracts, anterior and posterior segment vitrectomy. The system is designed for use in both anterior and posterior segment surgeries. It provides capabilities for phacoemulsification, coaxial and bimanual irrigation/aspiration, bipolar coagulation, vitrectomy, viscous fluid injection/removal and air/fluid exchange operations. The Stellaris Elite™ Vision Enhancement System configured with the laser module is additionally intended for retinal photocoagulation and laser trabeculoplasty.

The Bausch + Lomb posterior and combined procedure packs are intended for use with the Bausch + Lomb Stellaris Vision Enhancement Systems which are intended for the emulsification and removal of cataracts, anterior and posterior segment vitrectomy. They provide capabilities for phacoemulsification, coaxial and bimanual irrigation/aspiration, vitrectomy, and air/fluid exchange operations.

Light Pipes

The Bausch + Lomb Stellaris Elite™ Vision Enhancement System is intended for the emulsification and removal of cataracts, anterior and posterior segment vitrectomy. The system is designed for use in both anterior and posterior segment surgeries. It provides capabilities for phacoemulsification, coaxial and bimanual irrigation/aspiration, bipolar coagulation, vitrectomy, viscous fluid injection/removal and air/fluid exchange operations. The Stellaris Elite™ Vision Enhancement System configured with the laser module is additionally intended for retinal photocoagulation and laser trabeculoplasty.

The Bausch + Lomb Light Pipes are intended for use with the Bausch + Lomb Stellaris Vision Enhancement Systems for use during anterior and posterior segment surgeries.

7 Summary of Technological Characteristics

The following tables compare the subject devices, gamma-sterilized Stellaris Elite™ Packs and X-Pack Procedure Packs and the Light Pipe pouched with the ESA, to the predicate procedure packs of the Stellaris Elite™ vision enhancement systems. The technological characteristics of the Stellaris Elite™ vision enhancement system's reconfigured gamma-sterilized procedure packs and EO-sterilized Light Pipe and ESA pouches are substantially equivalent to the predicate devices.

Table 2: Substantial Equivalence Table for Subject Stellaris Elite™ and Stellaris PC (X-pack) Posterior and Combined Procedure Packs and Light Pipes, Predicate Stellaris Elite™ Vision Enhancement System (K162342)

Characteristic/ Parameter	Predicate Device: Stellaris Elite™ Vision Enhancement System (K162342)	Subject Device: Posterior And Combined Procedure Packs, and Light Pipes	Equivalency Analysis
Manufacturer	Bausch + Lomb, Inc	Same as Predicate Device	N/A
Regulation Number and Product Code	21 CFR 886.4670 (HQC) 21 CFR 886.4150 (HQE) 21 CFR 886.4390 (HQF)	**Procedure Packs**: 21 CFR 886.4670 (HQC) 21 CFR 886.4150 (HQE) **Light Pipes**: 21 CFR 876.1500 (MPA)	Identical
Device Class	II	II	Identical
Intended Use	Anterior/Posterior ophthalmic surgery	**Procedure Packs:** The Bausch + Lomb posterior/combined procedure packs contain a combination of components necessary for ophthalmic surgery and are intended for vitrectomy during posterior segment surgery. The Bausch + Lomb combined procedure packs are also intended for phacoemulsification of an opacified crystalline lens during combined surgery.	Same

Table 2: Substantial Equivalence Table for Subject Stellaris Elite™ and Stellaris PC (X-pack) Posterior and Combined Procedure Packs and Light Pipes, Predicate Stellaris Elite™ Vision Enhancement System (K162342)			
Characteristic/ Parameter	**Predicate Device: Stellaris Elite™ Vision Enhancement System (K162342)**	**Subject Device: Posterior And Combined Procedure Packs, and Light Pipes**	**Equivalency Analysis**
		Light Pipes: The Bausch + Lomb Light Pipes are intended to transmit light to the intraocular space during ophthalmic surgery.	
Indications for Use	The Bausch + Lomb Stellaris Elite™ Vision Enhancement System is intended for the emulsification and removal of cataracts, anterior and posterior segment vitrectomy. The system is designed for use in both anterior and posterior segment surgeries. It provides capabilities for phacoemulsification, coaxial and bimanual irrigation/aspiration, bipolar coagulation, vitrectomy, viscous fluid injection/removal and air/fluid exchange operations. The Stellaris Elite™ Vision Enhancement System configured with the laser module is additionally intended for retinal photocoagulation and laser trabeculoplasty.	**Procedure Packs:** The Bausch + Lomb Stellaris Elite™ Vision Enhancement System is intended for the emulsification and removal of cataracts, anterior and posterior segment vitrectomy. The system is designed for use in both anterior and posterior segment surgeries. It provides capabilities for phacoemulsification, coaxial and bimanual irrigation/aspiration, bipolar coagulation, vitrectomy, viscous fluid injection/removal and air/fluid exchange operations. The Stellaris Elite™ Vision Enhancement System configured with the laser module is additionally intended for retinal photocoagulation and laser trabeculoplasty. The Bausch + Lomb posterior and combined procedure packs are intended for use with the Bausch + Lomb Stellaris Vision Enhancement Systems which are intended for the emulsification and removal of cataracts, anterior and posterior segment vitrectomy. They provide capabilities for phacoemulsification, coaxial and bimanual irrigation/aspiration, vitrectomy, and air/fluid exchange operations. **Light Pipes:** The Bausch + Lomb Stellaris Elite™ Vision Enhancement System is intended for the emulsification and removal of cataracts, anterior and posterior	Same

Table 2: Substantial Equivalence Table for Subject Stellaris Elite™ and Stellaris PC (X-pack) Posterior and Combined Procedure Packs and Light Pipes, Predicate Stellaris Elite™ Vision Enhancement System (K162342)			
Characteristic/ Parameter	**Predicate Device: Stellaris Elite™ Vision Enhancement System (K162342)**	**Subject Device: Posterior And Combined Procedure Packs, and Light Pipes**	**Equivalency Analysis**
		segment vitrectomy. The system is designed for use in both anterior and posterior segment surgeries. It provides capabilities for phacoemulsification, coaxial and bimanual irrigation/aspiration, bipolar coagulation, vitrectomy, viscous fluid injection/removal and air/fluid exchange operations. The Stellaris Elite™ Vision Enhancement System configured with the laser module is additionally intended for retinal photocoagulation and laser trabeculoplasty. The Bausch + Lomb Light Pipes are intended for use with the Bausch + Lomb Stellaris Vision Enhancement Systems for use during anterior and posterior segment surgeries.	
Contents	Posterior/combined procedure packs contain a combination of components and accessories, including a Light Pipe, necessary for ophthalmic surgery.	Same as Predicate Device	Similar differences not affecting substantial equivalence, safety or performance
Gauge Sizes	23, 25, 27 gauge	Same as Predicate Device	Identical
Materials (Direct/Indirect Patient Contacting)	Materials of construction are biocompatible.	Same as Predicate Device	Identical
Packaging Configuration	High-Impact Polystyrene (HIPS) tray sealed with a Tyvek lid	**Procedure Packs:** Same as Predicate Device **Light Pipes:** Tyvek and Mylar film pouch	Similar, differences not affecting substantial equivalence, safety or performance
Shelf Life	36-months	18-months	Similar, differences not affecting substantial equivalence, safety or performance.
Single-Use	Yes	Same as Predicate Device	Identical
Provided Sterile	Yes	Same as Predicate Device	Identical
Sterilization Method	Gamma Irradiation or Ethylene Oxide	**Procedure Packs:** Gamma Irradiation	Same, differences not affecting substantial equivalence, safety

Table 2: Substantial Equivalence Table for Subject Stellaris Elite™ and Stellaris PC (X-pack) Posterior and Combined Procedure Packs and Light Pipes, Predicate Stellaris Elite™ Vision Enhancement System (K162342)			
Characteristic/ Parameter	**Predicate Device: Stellaris Elite™ Vision Enhancement System (K162342)**	**Subject Device: Posterior And Combined Procedure Packs, and Light Pipes**	**Equivalency Analysis**
		Light Pipes: Ethylene Oxide	or performance.
Sterilization Dose (kGy)	25-50 kGy	Same as Predicate Device	Identical
Sterility Assurance Level (SAL)	10^{-6}	Same as Predicate Device	Identical
Biocompatibility	Testing in accordance with ISO 10993-1:2018 guidance and FDA Guidance: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	Same as Predicate Device	Identical

8 Summary of Nonclinical Tests and Results

Transportation Testing

Transportation and Packaging assessment for the reconfigured procedure packs was performed in accordance with ISO 11607-1:2019. Transportation testing for the EO-sterilized pouches was performed in accordance with ISO 11607-1:2019 and ISO 11607-2:2019. Test results satisfied the acceptance criteria as defined by the associated ISO standard. Testing passed.

Sterilization Validation

Sterilization validation of the reconfigured gamma-sterilized procedure packs was performed in accordance with the requirements of EN ISO 11137-2. Sterilization validation of the EO-sterilized pouches was performed in accordance with 11135:2014+A1:2019. Test results satisfied the acceptance criteria as defined by the associated ISO standard. Testing passed.

Biocompatibility Testing

Biocompatibility assessments for the reconfigured gamma-sterilized procedure packs and Light Pipe pouches, were performed in accordance with the requirements of ISO 10993-1 to evaluate the impact of the patient contacting material. Test results satisfied the acceptance criteria as defined by the associated ISO standard. Testing passed.

Non-Clinical Performance Data

Non-clinical performance testing was performed to establish substantial equivalence between the predicate device and the revisions as identified within this premarket notification for phacoemulsification and vitrectomy procedures. Testing passed.

9 Summary of Animal/Clinical Tests and Results

Animal/Clinical Studies
No Animal or Clinical Study was performed.

10 Conclusion

The subject devices have the same intended use as the predicate devices and similar technological characteristics. The differences in technological characteristics do not raise new or different questions of safety and performance. Based on the results of the risk assessment and all applicable testing, the subject devices are determined to perform as intended during normal intended use for the emulsification and removal of cataracts, anterior and posterior segment vitrectomy. Therefore, the subject devices meet all applicable requirements for substantial equivalence when compared to the predicate devices.