April 7, 2026

BELKIN Vision Ltd. (a wholly owned subsidiary of Alcon Laboratories, Inc.)
% Anne-Marie Ripley
Clinical & Regulatory Affairs Consultant
Regulatory Pathways Group, Inc.
440 N. Barranca Ave., #2471
Covina, California 91723

Re: K252979
Trade/Device Name: Voyager DSLT (430840610)
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF
Dated: February 26, 2026
Received: February 26, 2026

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 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.	K252979

Please provide the device trade name(s).

Voyager DSLT (430840610)

Please provide your Indications for Use below.

The Voyager DSLT device is indicated for use in selective laser trabeculoplasty (SLT).

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY
K252979

I. Submitter Information

510(k) Owner: BELKIN Vision Ltd. (a wholly owned subsidiary of Alcon Laboratories, Inc.)
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+972-8-857-1619

Contact Person: Anne-Marie Ripley
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440 N. Barranca Ave., #2471
Covina, CA 91723
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Date Prepared: April 7, 2026

II. Device Name and Classification

Device Trade Name: Voyager DSLT (430840610)

Common Name: Ophthalmic laser

Classification Name: Ophthalmic laser

Regulation Number: 21 CFR 886.4390

Device Classification: Class 2

Product Code: HQF

III. Predicate Device and Reference Devices

Predicate Device

- BELKIN Eagle device (K230722)

IV. Device Description

The Voyager DSLT device is a Q-switched, 532 nm-wavelength, frequency-doubled Nd:YAG laser that is intended for use in performing selective laser trabeculoplasty. The laser spots produced by the Voyager DSLT device have a 400 µm spot size, a 3 ns pulse duration, and a 50-Hz pulse

repetition rate. The sequence of laser spots consists of 120 spots in a predefined circumferential elliptical pattern delivered at a pre-defined pulse energy level. The spots are delivered through the limbus to the trabecular meshwork in a non-contact fashion, without the need for the use of a contact gonioscopy lens. The device automatically locates the treatment location. The treatment location may be adjusted slightly by the operator. Once confirmed by the operator, the device then automatically applies the laser treatment sequence to the limbal region of the eye, while the eye tracker compensates for any eye movement. The default energy setting is 1.8 mJ/pulse.

V. Indications for Use

The Voyager DSLT device is indicated for use in selective laser trabeculoplasty (SLT).

VI. Comparison of Technological Characteristics with the Predicate Device

The Voyager DSLT has the same intended use, indications for use, target tissue, laser parameters, and laser pattern as the predicate device. It also has the same method of maintaining laser beam targeting and laser delivery as the predicate Eagle device. Refer to the Table below.

Characteristic	**Voyager DSLT (BELKIN Vision)** **Subject Device**	**Eagle (BELKIN Vision)** **Predicate Device** **K230722**	**Comparison of Subject and Predicate Devices**
Device Class	2	2	Same
Classification Product Code	HQF	HQF	Same
Regulation Number	886.4390	886.4390	Same
Intended Use	Selective Laser Trabeculoplasty (SLT)	Selective Laser Trabeculoplasty (SLT)	Same
Indications for use	Selective laser trabeculoplasty (SLT)	Selective laser trabeculoplasty (SLT)	Same
Laser Parameters			
Laser type	Q-switched, frequency-doubled Nd:YAG	Q-switched, frequency-doubled Nd:YAG	Same
Wavelength	532 nm	532 nm	Same
Laser pulse duration	3 ns	3 ns	Same
Pulse energy range	1.1 – 1.9 mJ	1.1 – 1.9 mJ	Same
Pulse repetition rate	50 Hz	50 Hz	Same
Laser Beam Delivery			

Characteristic	Voyager DSLT (BELKIN Vision) Subject Device	Eagle (BELKIN Vision) Predicate Device K230722	Comparison of Subject and Predicate Devices
Method of laser delivery (pattern)	Automated delivery of laser spots in a pre-defined pattern (360° ellipse) through the limbus without the use of a contact gonioscopy lens; the trabecular meshwork (TM) is not directly visualized as laser spots are applied.	Automated delivery of laser spots in a pre-defined pattern (360° ellipse) through the limbus without the use of a contact gonioscopy lens; the trabecular meshwork (TM) is not directly visualized as laser spots are applied.	Same
Target tissue	Trabecular meshwork	Trabecular meshwork	Same
Method of maintaining laser beam targeting	Anatomical detection algorithm and eye tracking to compensate for eye movements during the procedure.	Anatomical detection algorithm and eye tracking to compensate for eye movements during the procedure.	Same
Spot diameter	400 µm	400 µm	Same
Auxiliary optical characteristics			
Aiming laser	Diode laser	Diode laser	Same
Aiming wavelength	635 nm	635 nm	Same
Method of maintaining the focal position of treatment beam	Manually set using a joystick to adjust the axial position by visualizing the overlap of two ranging (650 nm) diode laser beams.	Manually set using a joystick to adjust the axial position by visualizing the overlap of two ranging (650 nm) diode laser beams.	Same
Illumination	LED illumination ring, visible white light	LED illumination ring, visible white light	Same
Physical Dimensions			
System weight	34 kg / 74 lbs.	34 kg / 74 lbs.	Same
System dimensions (H x W X D)	52 x 53 x 63 cm 20.5 x 21.8 x 25 inches	52 x 53 x 63 cm 20.5 x 21.8 x 25 inches	Same

The software of the Voyager DSLT device was updated to incorporate 3 changes:

1. Addition of the "Complete an Incomplete Treatment" feature: This feature allows the user to complete a procedure that was interrupted and not fully completed.
2. Modifications to the Target Definition screen to remind the user to ensure proper target definition, and to provide options to the user for how the target definition ring is displayed and for editing the target definition.
3. Automatically add results of the test card daily check to the exported treatment record

These changes did not raise new types of questions regarding the safety and effectiveness of the device.

VII. Summary of Non-Clinical Testing

Based on the risk assessment and design control requirements, the following verification and validation testing/analysis was performed:

- Bench testing was performed to demonstrate the ability of the Voyager DSLT to properly align the target definition ring between the original and new procedure, when completing an incomplete procedure.
- An analysis of the changes on human factors was conducted per FDA guidance, "Applying Human Factors and Usability Engineering to Medical Devices"
- Animal testing, performed to support 510(k) clearance of the predicate Eagle device (K230722), also supports the safety of the added "Complete an Incomplete Treatment" feature.
- Software verification and validation testing: BELKIN developed and verified the software in accordance with a major level of concern described in the FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and also per the IEC 62304: 2015 Medical Device Software - Software Life Cycle Processes standard.

Results of the non-clinical testing support a substantial equivalence determination. The Voyager DSLT device is substantially equivalent to its predicate device for the indications for use.

VIII. Conclusions

The Voyager DSLT device has the same indications for use as the predicate device. The differences in technological characteristics of the Voyager device do not raise new or different types of questions of safety or effectiveness. The results of the non-clinical performance testing demonstrate that the Voyager DSLT device functions as intended and is substantially equivalent to the predicate device.