December 8, 2023

BELKIN Vision Ltd.
% Anne-Marie Ripley
Clinical & Regulatory Consultant
Regulatory Pathways Group, Inc.
440 N. Barranca Ave., #2471
Covina, California 91723

Re: K230722
Trade/Device Name: Eagle Device
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF
Dated: November 2, 2023
Received: November 2, 2023

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.

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

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)*
K230722

Device Name
Eagle device

Indications for Use *(Describe)*
The Eagle device is indicated for use in selective laser trabeculoplasty (SLT).

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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510(k) SUMMARY
K230722

I. Submitter Information

510(k) Owner: BELKIN Vision Ltd.
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Contact Person: Anne-Marie Ripley
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Date Prepared: December 8, 2023

II. Device Name and Classification

Device Trade Name: Eagle device

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

- Lumenis Selecta Duet LED (K220877)

Reference Devices

- Topcon PSLT for PASCAL Streamline (K171488)
- OD-OS Navilas Laser System 577s (K162191)

Topcon PSLT for PASCAL Streamline (K171488) supports automated delivery of laser spots in a pre-defined pattern for SLT indications and high pulse repetition rate laser spots.

OD-OS Navilas Laser System 577s (K162191), which allows for laser treatment to the retina using an automated delivery system with eye tracking, supports algorithms for eye tracking to ensure that the laser beam position is maintained at the desired treatment location throughout the laser treatment.

IV. Device Description

The Eagle 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 Eagle 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. Intended Use and Indications for Use

The Eagle device is a prescription device intended to coagulate or cut tissue of the eye, orbit, or surrounding skin by a laser beam. The Eagle device has the same intended use as the predicate device. The Eagle device has the following Indications for Use (IFU) statement:

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

The IFU statement of the Eagle device is not substantially different from that of the predicate device. The non-substantial difference in the IFU statement for the Eagle versus the predicate

device is that the IFU statement for the Eagle device is narrower; it does not include posterior capsulotomy, pupillary membranectomy in aphakic and pseudophakic patients, and iridotomy.

VI. Comparison of Technological Characteristics with the Predicate Device

Although the Eagle device and the predicate do not share identical technological characteristics, these differences do not raise different types of questions of safety and effectiveness.

Characteristic	**Subject Device** **BELKIN Vision Eagle device** **K230722**	**Predicate Device** **Lumenis Be Inc. Selecta Duet LED** **K220877**	**Comparison of Subject Device to Predicate Device**
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	Same
Indications for use	Selective laser trabeculoplasty (SLT).	In SLT mode: **Selective laser trabeculoplasty (SLT)** In YAG mode: Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discission of the posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy/iridectomy	Different, but the differences do not raise different types of questions of safety and effectiveness. Both devices are indicated for SLT.
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

Characteristic	Subject Device BELKIN Vision Eagle device K230722	Predicate Device Lumenis Be Inc. Selecta Duet LED K220877	Comparison of Subject Device to Predicate Device
Pulse energy range	1.1 – 1.9 mJ	0.3 – 2.6 mJ	Different, but the difference does not raise different types of questions of safety and effectiveness. The pulse energy range of Subject Device is within the energy range of the Predicate Device. The energy level of the subject device is fixed for the entire set of 120 spots while the energy level of the predicate device may be changed as laser spots are applied to the trabecular meshwork (TM). The safety and effectiveness of the Eagle device's pulse energy range were supported by non-clinical and clinical performance data.
Pulse repetition rate	50 Hz	Up to 3 Hz	Different, but the difference does not raise different types of questions of safety and effectiveness. The safety and effectiveness of the Eagle device's 50-Hz pulse repetition rate were supported by non-clinical and clinical performance data.
Laser Beam Delivery			
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.	Manual delivery of laser spots through a contact gonioscopy lens to directly visualize the TM. Spots are applied for usually 180° or 360° of the TM.	Same pattern (i.e. 360° ellipse) Method of delivery is different, but the difference does not raise different types of questions of safety and effectiveness. The safety and effectiveness of the Eagle device's automated delivery were supported by non-clinical and clinical performance data.
Target tissue	Trabecular meshwork	Trabecular meshwork	Same

Characteristic	Subject Device BELKIN Vision Eagle device K230722	Predicate Device Lumenis Be Inc. Selecta Duet LED K220877	Comparison of Subject Device to Predicate Device
Method of maintaining laser beam targeting	Anatomical detection algorithm and eye tracking to compensate for eye movements during the procedure.	Direct visualization of aiming beam and target tissue through slit lamp microscope and handheld gonioscope contact lens.	Different, but the difference does not raise different types of questions of safety and effectiveness. Reference Device 2 supports the bench testing methods used to demonstrate the safety and effectiveness of this technological feature.
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 using aiming beam and microscope image as a guide.	Similar
Illumination	LED illumination ring, visible white light	LED illumination source, both visible white light and filtered light	Similar
Physical dimensions			
System weight	30 kg / 66 lbs	31 kg / 68 lbs	Similar
System dimensions (H x W X D)	52 x 53 x 63 cm 20.5 x 21.8 x 25 inches	57 x 75 x 44 cm, 23 x 30 x 18 inches	Similar

VII. Summary of Non-Clinical Testing

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

- Device performance testing
- Validation of laser fluence delivery to the target tissue
- Environmental and transportation testing were conducted per elements of:
    - ASTM D4332-14 Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing

    - ASTM D6653-13 - Standard Test Methods for Determining the Effects of High Altitude on Packaging Systems by Vacuum Method
    - ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems (Assurance Level II)
    - ASTM D5276-19 - Standard Test Method for Drop Test of Loaded Containers by Free Fall
    - ASTM D4728-17 - Standard Test Method for Random Vibration Testing of Shipping Containers
- Laser and optical radiation hazard evaluation and safety testing was conducted per:
    - IEC 60601-2-22: 2007 (3rd Ed.) Medical electrical equipment Part 2: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
    - IEC 60825-1:2014 Safety of laser products – Part 1: Equipment classification and requirements
- Product reliability testing was conducted per Telcordia SR-332.
- Biocompatibility testing: The biocompatibility profile of the tissue contacting components of the device were assessed for cytotoxicity, sensitization (Guinea pig maximization) and intracutaneous reactivity testing as recommended by FDA's 2020 Biocompatibility Guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" and relevant parts of International Standard Organization (ISO) 10993 Biological evaluation of medical devices standard series.
- 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 62304:2006 and A1:2015 Medical Device Software - Software Life Cycle Processes standard.
- Electromagnetic compatibility (EMC) was conducted per IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for safety and essential performance – Collateral Standard: Electromagnetic compatibility – Requirements and tests.
- Electrical safety testing was conducted per IEC 60601-1:2005 + CORR1:2006 + CORR2:2007 + AMD1:2012 Medical electrical equipment – Part 1: General requirements for safety 1: collateral standard: Safety Requirements for Medical Electrical Systems.
- Human factors testing was conducted per
    - FDA guidance, "Applying Human Factors and Usability Engineering to Medical Devices"
    - ANSI/AAMI IEC 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices, and
    - IEC 60601-1-6 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- Animal testing was conducted per 21 CFR Part 58 (Good Laboratory Practices) in rabbit to evaluate the acute and subacute safety of the device compared to the standard

selective laser trabeculoplasty (SLT). Macroscopic and microscopic treatment-related changes were comparable in eyes undergoing SLT with the Eagle device and the SLT comparator device. Mild changes were limited in acute phase and resolved by day 29. The study provides evidence to support the substantial equivalence of the Eagle device to the predicate device in post-treatment tissue reactions.

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

VIII. Clinical Performance Testing

A prospective, multi-center, randomized, controlled trial was conducted to evaluate the safety and effectiveness of laser trabeculoplasty using the Eagle device to compared to conventional selective laser trabeculoplasty (SLT). 276 participants age 40 years or older with primary open-angle glaucoma, pseudoexfoliation glaucoma, pigmentary glaucoma, or ocular hypertension on three or fewer IOP-lowering medications at baseline were enrolled across 14 sites. Prior incisional or laser-based glaucoma procedures, severe glaucoma in either eye, dense pigmentation or hemorrhage in the perilimbal conjunctival area or anterior sclera were exclusionary. Eligible participants underwent baseline IOP-lowering medication washout and those with post-washout IOP between 22 – 35 mmHg were randomized 1:1 to 360° treatment with either the Eagle device or with a conventional SLT device. Participants were followed for 12 months post-treatment. The primary effectiveness endpoint was the between-group difference in the mean change in unmedicated IOP at 6 months compared to baseline. The primary safety outcome was the rate of ocular adverse events (AEs) in each treatment group at or prior to 12 months.

A total of 196 participants were enrolled and randomized, 99 to Eagle and 97 to conventional SLT. Of these, 187 participants, 96 Eagle and 91 conventional SLT, underwent the assigned laser procedure. The mean age of participants was 65.6 ± 9.4 years (range 40 – 88 years) and 39.0% were women. 98% of participants were white, 1% were Black, 0.5% were Asian and 0.5% were mixed race. 87% of participants had glaucoma. 73% had primary open angle glaucoma, 11% had pseudoexfoliative glaucoma and 3% had pigmentary glaucoma. The remaining 13% of participants had ocular hypertension. Mean screening IOP was 21.5 ± 5.4 mmHg for the Eagle group and 20.5 ± 4.5 mmHg for the conventional SLT group. At the time of enrollment, 32.2% of participants were not taking any hypotensive medications. The average number of ocular hypotensive medications at screening was 1.2 ± 1.0 for the Eagle group compared to 1.1 ± 1.0 for the SLT group. Post-washout baseline IOP was 26.5 ± 3.6 mmHg in the Eagle group and 25.8 ± 3.6 mmHg in the SLT group.

Effectiveness

The Eagle procedure provided a mean (±SE per the least-square estimation) reduction of unmedicated IOP at 6 months of 5.5 ± 0.5 mmHg (95% CI -6.5 to -4.5), compared with 6.3 ± 0.5 mmHg (95% CI -7.3 to -5.2) in the conventional SLT group (Table 1). The difference in mean

reduction in IOP between the two groups (SLT-Eagle) was -0.80 mmHg (95% CI -2.28 to 0.68 mmHg). Table 2 presents the primary effectiveness endpoint analysis for the Eagle group, stratified by the energy level used.

Table 1: Primary Effectiveness Endpoint
6 Month Unmedicated IOP Change from Baseline
Primary Analysis[1] per Least Squares Estimation of ANCOVA Model[2]

Method	Eagle N Mean ± SE[3] (95% CI)	SLT N Mean ± SE[3] (95% CI)	ANCOVA p-value[2] p-value H0: Δ ≤ -1.95 mmHg Ha: Δ > -1.95 mmHg Δ = Difference in Mean (SLT – Eagle)
ITT Population[4] (N= 196)			
Primary Analysis	99 -4.63 ± 0.49 (-5.60, -3.67)	97 -5.70 ± 0.50 (-6.69, -4.71)	0.209
Difference in mean = SLT – Eagle (95% CI)	-1.07 (-2.45, 0.32)		
mPP Population[5] (N= 152)			
Primary Analysis	77 -5.48 ± 0.52 (-6.52, -4.45)	75 -6.29 ± 0.53 (-7.34, -5.23)	0.127
Difference in mean = SLT – Eagle (95% CI)	-0.80 (-2.28, 0.68)		

1 Baseline value was used to impute 6-month for participants with SSI or unsafe to washout at 6 months. The SSIs were defined as surgical procedures that might affect the level of IOP (such as iridotomy, iridectomy, trabeculectomy, glaucoma shunt implantation, argon laser trabeculoplasty, selective laser trabeculoplasty, cataract surgery, or other surgery that might affect IOP).

2 ANCOVA Model: $Yij = \mu + ti + ß*(Xij – \text{average of } Xij) + rj + eij$, Yij is the change-from-baseline IOP (the 6-month IOP value was subtracted from baseline IOP for each eye) for treatment i and study eye j, Xij is the corresponding baseline IOP measurement, μ is the overall mean, ti is the treatment indicator, ß is the effect of baseline IOP, rj is an indicator of beta-blocker use in the fellow eye, and eij is the error term.

3 Standard Error (i.e., standard deviation of mean)

4 The ITT Population is defined as all randomized participants.

5 The Modified Per Protocol (mPP) population included participants who met the Per Protocol (PP) definition. In addition, participants who met any of the following criteria during the first 6 months were included in the mPP population as failures: Had a secondary surgical intervention (SSI) in the study eye that could affect IOP; had an ocular SAE in the study eye; or participant for whom 6-month washout was considered unsafe. For these participants, 6-month IOP was imputed with their baseline IOP measurement for the primary endpoint analysis. Participants who were missing their 6-month data for other reasons were not included in the mPP population.
Per protocol (PP) was defined as all enrolled and randomized participants who were treated and for whom data concerning the primary effectiveness endpoint measure was available and who had no major protocol deviations/violations (e.g. inclusion and/or exclusion criteria violations, treatment not according to randomization, IOP measured in an unmasked fashion). Participants with major protocol deviations were excluded from the PP population.

Table 2: Primary Effectiveness Endpoint, Stratified by Energy Level (Eagle Group Only)
6 Month Unmedicated IOP Change from Baseline
Primary Analysis[1] per Least Squares Estimation of ANCOVA Model[4]

Primary Effectiveness Endpoint	1.1 mJ/shot	1.2 mJ/shot	1.3 mJ/shot	1.4 mJ/shot	1.5 mJ/shot	1.6 mJ/shot	1.7 mJ/shot	1.8 mJ/shot	1.9 mJ/shot
ITT Population[2]									
N	**4**	**2**	**1**	**4**	**7**	**9**	**39**	**26**	**4**
Change in unmedicated IOP from baseline to 6 months (mmHg) Mean (SE)[3]	-5.29 ± 2.51 (-10.29, -0.29)	-7.66 ± 3.45 (-14.52, -0.79)	-8.63 ± 4.95 (-18.47, 1.20)	-6.10 ± 2.44 (-10.96, -1.24)	-1.88 ± 1.85 (-5.57, 1.80)	-7.23 ± 1.64 (-10.50, -3.96)	-4.93 ± 0.78 (-6.49, -3.38)	-3.40 ± 0.95 (-5.30, -1.51)	-4.87 ± 2.48 (-9.81, 0.07)
mPP Population[5]									
N	**4**	**2**	**1**	**2**	**3**	**9**	**33**	**20**	**3**
Change in unmedicated IOP from baseline to 6 months (mmHg) Mean (SE)[3]	-4.83 ± 2.53 (-9.88, 0.23)	-7.36 ± 3.46 (-14.27, -0.45)	-8.52 ± 4.95 (-18.40, 1.37)	-7.83 ± 3.45 (-14.72, -0.95)	-5.32 ± 2.83 (-10.96, 0.33)	-7.28 ± 1.64 (-10.56, -4.00)	-5.50 ± 0.85 (-7.19, -3.80)	-4.30 ± 1.10 (-6.50, -2.11)	-7.30 ± 2.87 (-13.03, -1.58)

1 Baseline value was used to impute 6-month for participants with SSI or unsafe to washout at 6 months. The SSIs were defined as surgical procedures that might affect the level of IOP (such as, iridotomy, iridectomy, trabeculectomy, glaucoma shunt implantation, argon laser trabeculoplasty, selective laser trabeculoplasty, cataract surgery), or other surgery that might affect IOP.

2 The ITT Population is defined as all randomized participants. Three Eagle subjects were excluded from the ITT analysis because they did not undergo the assigned laser procedure.

3 Standard Error (i.e., standard deviation of mean)

4 ANCOVA Model: $Yij = \mu + ti + ß*(Xij - \text{average of } Xij) + rj + eij$, Yij is the change-from-baseline IOP (the 6-month IOP value was subtracted from baseline IOP for each eye) for energy level i and study eye j, Xij is the corresponding baseline IOP measurement, μ is the overall mean, ti is the energy level indicator, ß is the effect of baseline IOP, rj is an indicator of beta-blocker use in the fellow eye, and eij is the error term.

5 The Modified Per Protocol (mPP) population included participants who met the Per Protocol (PP) definition. In addition, participants who met any of the following criteria during the first 6 months were included in the mPP population as failures: Had a secondary surgical intervention (SSI) in the study eye that could affect IOP; had an ocular SAE in the study eye; or participant for whom 6-month washout was considered unsafe. For these participants, 6-month IOP was imputed with their baseline IOP measurement for the primary endpoint analysis. Participants who were missing their 6-month data for other reasons were not included in the mPP population.

Per protocol (PP) was defined as all enrolled and randomized participants who were treated and for whom data concerning the primary effectiveness endpoint measure was available and who had no major protocol deviations/violations (e.g. inclusion and/or exclusion criteria violations, treatment not according to randomization, IOP measured in an unmasked fashion). Participants with major protocol deviations were excluded from the PP population.

Safety

No ocular serious adverse events (SAEs) were reported in the first six months. One ocular SAE of subluxation of a pre-existing intraocular lens (IOL) was reported in one participant in the conventional SLT group on post-procedure day 1, which was corrected with surgical repositioning. One ocular SAE was reported in an Eagle group participant who experienced a decline in visual field due to non-glaucomatous acute optic neuropathy at the 12-month follow-up visit.

The most commonly reported non-serious AE was punctate subconjunctival hemorrhage (21% in the Eagle group vs 1% in the conventional SLT group). These events resolved without clinical sequelae. Elevated IOP was reported in two participants in the Eagle group and two participants in the conventional SLT group. The proportion of participants with a worsening of visual field mean deviation by ≥2.5 dB was 6.6% and 9.9% in the Eagle group vs. 12.6% and 15.7% in the conventional SLT group at 6 and 12 months, respectively. In the first six months, progression of cataracts was reported in three Eagle participants and one conventional SLT participant. Between 6 and 12 months, three Eagle and four conventional SLT participants had progression of cataracts and one conventional SLT participant developed a new cataract.

Secondary surgical interventions (SSIs) were reported in four Eagle participants (trabeculectomy [N=1], cataract surgery [N=2], and laser retinopexy [N=1] to repair a retinal tear) and three conventional SLT participants (cataract surgeries [N=2], IOL repositioning [N=1]). Table 3 and Table 4 present study eye ocular AEs within the first 6 months and between 6-12 months, respectively. Ocular adverse events in the study eye are shown stratified by energy level in Tables 7 and 8.

Anterior chamber (AC) cells and flare findings at each study visit for change from screening in are shown in Tables 5 and 6. Mild corneal haze was reported in one Eagle participant at Month 12. No moderate or severe corneal haze was reported in either group. At the 12-month assessment of 5-minute delayed corneal staining, 17% of the Eagle participants and 20% of the conventional SLT participants had staining in one quadrant. 5% of the Eagle participants and 4% of the conventional SLT participants had staining in two quadrants. No participants in either group had staining in three or more quadrants. Conjunctival staining scores at Month 12 were 2.11±3.01 in the Eagle group and 1.83±2.22 in the conventional SLT group.

Table 3: Study Eye Adverse Events from 0-6 Months (Safety Population)

Ocular Events	Eagle N = 96		SLT N = 91	
	# of Events	n (%)	# of Events	n (%)
Serious Adverse Events	**—**	**—**	**1**	**1 (1.1%)**
Subluxation of intra-ocular lens	—	—	1	1 (1.1%)
Non-Serious Adverse Events	**44**	**34 (35.4%)**	**26**	**20 (22.0%)**
Subconjunctival hemorrhage, punctate	20	20 (20.8%)	1	1 (1.1%)
Foreign body sensation	3	3 (3.1%)	3	3 (3.3%)
Cataract progression	3[3]	3 (3.1%)	1	1 (1.1%)
Superficial punctate keratitis	2	2 (2.1%)	4	4 (4.4%)
Elevated IOP (IOP increase from baseline ≥ 10 mmHg)	2	2 (2.1%)	2	2 (2.2%)
Conjunctivitis	2	2 (2.1%)	—	—
Mild or moderate anterior chamber inflammation	1	1 (1.0%)	3	3 (3.3%)
Transient blurred vision	1	1 (1.0%)	2	2 (2.2%)
Corneal erosion	1	1 (1.0%)	1	1 (1.1%)
Eye discharge	1	1 (1.0%)	1	1 (1.1%)
Eye discomfort	1	1 (1.0%)	1	1 (1.1%)
Eye pain	1	1 (1.0%)	1	1 (1.1%)
Hordeolum externum	1	1 (1.0%)	1	1 (1.1%)
Blepharitis	1	1 (1.0%)	—	—
Eye itchiness	1	1 (1.0%)	—	—
Periodical hyperlacrimation	1	1 (1.0%)	—	—
Retinal tear	1	1 (1.0%)	—	—
Subconjunctival hemorrhage, moderate	1	1 (1.0%)	—	—
Cystoid macular edema	—	—	1	1 (1.1%)
Elevated IOP (IOP increase from baseline < 10 mmHg)[2]	—	—	1	1 (1.1%)
Eye burning sensation	—	—	1	1 (1.1%)
Floater	—	—	1	1 (1.1%)
Periorbital pain	—	—	1	1 (1.1%)
Any adverse events	**44**	**34 (35.4%)**	**27**	**20 (22.0%)**
Any adverse events (excluding Subconjunctival hemorrhage, punctate)	**24**	**19 (19.8%)**	**26**	**19 (20.9%)**

The counts (n) are the number of participants reported with the corresponding events. % = n / N x 100%. Multiple events could be reported for the same participant.

[1] Miettinen-Nurminen method

[2] One SLT participant was reported with a post-treatment AE of 'elevated IOP' before the 6-Month visit (Day 199), although the IOP was NOT elevated >10 mmHg more than baseline.

[3] One Eagle participant was reported to have a cataract at the 6-month visit and subsequently underwent cataract surgery. However, this participant's cataract was pre-existing with severe opacity (3+) at the time of enrollment. A protocol deviation was reported for enrollment of this participant despite them having a pre-existing severe cataract.

Table 4: Study Eye Adverse Events from 6-12 Months (Safety Population)

Ocular Events	Eagle N = 96		SLT N = 91	
	# of Events	n (%)	# of Events	n (%)
Serious Adverse Events	**1**	**1 (1.0%)**	**—**	**—**
Acute optic neuropathy	1	1 (1.0%)	—	—
Non-Serious Adverse Events	**7**	**6 (6.3%)**	**7**	**7 (7.7%)**
Cataract progression	3	3 (3.1%)	4	4 (4.4%)
Conjunctivitis	1	1 (1.0%)	—	—
Diabetic retinopathy	1	1 (1.0%)	—	—
Elevated IOP (IOP increase from baseline ≥ 10 mmHg)[2]	1	1 (1.0%)	—	—
Foreign body sensation	1	1 (1.0%)	—	—
Cataract	—	—	1	1 (1.1%)
Cataract surgery	—	—	1	1 (1.1%)
Guttata	—	—	1	1 (1.1%)
Any adverse events	**8**	**7 (7.3%)**	**7**	**7 (7.7%)**

The counts (n) are the number of participants reported with the corresponding events. % = n / N x 100%. Multiple events could be reported for the same participant.

[1] Miettinen-Nurminen method

[2] Steroid-induced elevated IOP occurred in one Eagle participant and was due to use of nasal steroid. This participant had a similar event during the first 6 months.

Table 5: Slit Lamp Examination – Change in Anterior Chamber Cells from Screening by Visit (Safety Population)

	Post Procedure n (%)	1D n (%)	7D n (%)	1M n (%)	3M n (%)	6M n (%)	12M n (%)
Eagle (96 Eyes)							
N	96	95	94	94	92	91	88
Increase by +3	3 (3.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Increase by +2	6 (6.3%)	5 (5.3%)	1 (1.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Increase by +1	16 (16.7%)	3 (3.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Increase by +0.5	5 (5.2%)	10 (10.5%)	2 (2.1%)	0 (0.0%)	0 (0.0%)	1 (1.1%)	1 (1.1%)
No Change	66 (68.8%)	77 (81.1%)	91 (95.8%)	94 (100.0%)	92 (100.0%)	90 (97.8%)	81 (92.0%)
Decrease by +0.5	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.1%)
Decrease by +1	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (5.7%)
Decrease by +2	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Increase +0.5 or more (95% CI)[1]	30 (31.3%) (22.2%, 41.5%)	18 (18.9%) (11.6%, 28.3%)	3 (3.2%) (0.7%, 9.0%)	0 (0.0%) (0.0%, 3.8%)	0 (0.0%) (0.0%, 3.9%)	1 (1.1%) (0.0%, 5.9%)	1 (1.1%) (0.0%, 6.2%)
Not Reported	0	0	1	0	0	1	0
Total	96	95	95	94	92	92	88
SLT (91 Eyes)							
N	89	90	91	89	87	86	81
Increase by +3	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Increase by +2	1 (1.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Increase by +1	9 (9.9%)	3 (3.3%)	2 (2.2%)	1 (1.1%)	1 (1.1%)	1 (1.2%)	1 (1.2%)
Increase by +0.5	9 (9.9%)	8 (8.8%)	1 (1.1%)	1 (1.1%)	0 (0.0%)	0 (0.0%)	1 (1.2%)
No Change	70 (76.9%)	79 (86.8%)	88 (96.7%)	87 (97.8%)	86 (98.9%)	85 (98.8%)	75 (91.5%)
Decrease by +0.5	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (2.4%)
Decrease by +1	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (2.4%)
Decrease by +2	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Increase +0.5 or more (95% CI)[1]	19 (20.9%) (13.1%, 30.7%)	11 (12.1%) (6.2%, 20.6%)	3 (3.3%) (0.7%, 9.3%)	2 (2.2%) (0.3%, 7.9%)	1 (1.1%) (0.0%, 6.2%)	1 (1.2%) (0.0%, 6.3%)	2 (2.4%) (0.3%, 8.5%)
Not Reported	2	1	0	0	0	0	1
Total	91	91	91	89	87	86	82

[1] Binomial distribution

Table 6: Slit Lamp Examination – Change in Anterior Chamber Flare from Screening by Visit (Safety Population)

	Post Procedure n (%)	1D n (%)	7D n (%)	1M n (%)	3M n (%)	6M n (%)	12M n (%)
Eagle (96 Eyes)							
N	96	95	94	94	92	91	88
Increase by +3	1 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Increase by +2	2 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Increase by +1	9 (9.4%)	11 (11.6%)	2 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Increase by +0.5	8 (8.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.1%)	1 (1.1%)
No Change	76 (79.2%)	84 (88.4%)	92 (96.8%)	94 (100.0%)	92 (100.0%)	90 (97.8%)	82 (93.2%)
Decrease by +0.5	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (2.3%)
Decrease by +1	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (3.4%)
Decrease by +2	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Increase +0.5 or more (95% CI)[1]	20 (20.8%) (13.2%, 30.3%)	11 (11.6%) (5.9%, 19.8%)	2 (2.1%) (0.3%, 7.4%)	0 (0.0%) (0.0%, 3.8%)	0 (0.0%) (0.0%, 3.9%)	1 (1.1%) (0.0%, 5.9%)	1 (1.1%) (0.0%, 6.2%)
Not Reported	0	0	1	0	0	1	0
Total	96	95	95	94	92	92	88
SLT (91 Eyes)							
N	89	90	91	89	87	86	81
Increase by +3	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Increase by +2	1 (1.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Increase by +1	8 (8.8%)	2 (2.2%)	1 (1.1%)	1 (1.1%)	1 (1.1%)	1 (1.2%)	1 (1.2%)
Increase by +0.5	6 (6.6%)	5 (5.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
No Change	74 (81.3%)	82 (90.1%)	89 (97.8%)	87 (97.8%)	85 (97.7%)	84 (97.7%)	75 (91.5%)
Decrease by +0.5	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.2%)
Decrease by +1	0 (0.0%)	1 (1.1%)	1 (1.1%)	1 (1.1%)	1 (1.1%)	1 (1.2%)	4 (4.9%)
Decrease by +2	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Increase +0.5 or more (95% CI)[1]	15 (16.5%) (9.5%, 25.7%)	7 (7.7%) (3.1%, 15.2%)	1 (1.1%) (0.0%, 6.0%)	1 (1.1%) (0.0%, 6.1%)	1 (1.1%) (0.0%, 6.2%)	1 (1.2%) (0.0%, 6.3%)	1 (1.2%) (0.0%, 6.6%)
Not Reported	2	1	0	0	0	0	1
Total	91	91	91	89	87	86	82

[1] Binomial distribution

Table 7: Study Eye Adverse Events at ≤6 Months, Stratified by Energy Level (Eagle Group Only) (Safety Population)

Ocular Events	1.1 mJ/shot N = 4 n (%)	1.2 mJ/shot N = 2 n (%)	1.3 mJ/shot N = 1 n (%)	1.4 mJ/shot N = 4 n (%)	1.5 mJ/shot N = 7 n (%)	1.6 mJ/shot N = 9 n (%)	1.7 mJ/shot N = 39 n (%)	1.8 mJ/shot N = 26 n (%)	1.9 mJ/shot N = 4 n (%)	Total N = 96 n (%)
Non-Serious Adverse Events	**—**	**—**	**1 (100.0%)**	**1 (25.0%)**	**2 (28.6%)**	**4 (44.4%)**	**10 (25.6%)**	**15 (57.7%)**	**1 (25.0%)**	**34 (35.4%)**
Blepharitis	—	—	—	—	—	—	—	1 (3.8%)	—	1 (1.0%)
Cataract progression	—	—	—	—	—	1 (11.1%)	—	2 (7.7%)	—	3 (3.1%)
Conjunctivitis	—	—	—	—	—	1 (11.1%)	1 (2.6%)	—	—	2 (2.1%)
Corneal erosion	—	—	—	—	—	—	1 (2.6%)	—	—	1 (1.0%)
Elevated IOP	—	—	—	—	1 (14.3%)	—	—	1 (3.8%)	—	2 (2.1%)
Eye discharge	—	—	—	—	—	—	1 (2.6%)	—	—	1 (1.0%)
Eye discomfort	—	—	—	—	—	—	—	1 (3.8%)	—	1 (1.0%)
Eye itchiness	—	—	—	—	—	—	—	1 (3.8%)	—	1 (1.0%)
Eye pain	—	—	—	—	—	—	—	1 (3.8%)	—	1 (1.0%)
Foreign body sensation	—	—	—	1 (25.0%)	—	—	1 (2.6%)	1 (3.8%)	—	3 (3.1%)
Hordeolum externum	—	—	—	—	—	—	—	—	1 (25.0%)	1 (1.0%)
Mild or moderate anterior chamber inflammation	—	—	—	—	—	—	—	1 (3.8%)	—	1 (1.0%)
Periodical hyperlacrimation	—	—	—	—	—	—	1 (2.6%)	—	—	1 (1.0%)
Retinal tear	—	—	—	—	—	—	—	1 (3.8%)	—	1 (1.0%)
Subconjunctival hemorrhage, moderate	—	—	—	—	—	1 (11.1%)	—	—	—	1 (1.0%)
Subconjunctival hemorrhage, punctate	—	—	1 (100.0%)	—	2 (28.6%)	1 (11.1%)	7 (17.9%)	9 (34.6%)	—	20 (20.8%)
Superficial punctate keratitis	—	—	—	—	—	—	—	2 (7.7%)	—	2 (2.1%)
Transient blurred vision	—	—	—	1 (25.0%)	—	—	—	—	—	1 (1.0%)
Any adverse events	**0 Reports from 0 participants 0.0%**	**0 Reports from 0 participants 0.0%**	**1 Reports from 1 participant 100.0%**	**2 Reports from 1 participant 25.0%**	**3 Reports from 2 participants 28.6%**	**4 Reports from 4 participants 44.4%**	**12 Reports from 10 participants 25.6%**	**21 Reports from 15 participants 57.7%**	**1 Reports from 1 participant 25.0%**	**44 Reports from 34 participants 35.4%**

The counts (n) are the number of participants reported with the corresponding events. % = n / N x 100%.
Multiple events could be reported for the same participant.

Table 8: Study Eye Adverse Events at >6 Months, Stratified by Energy Level (Eagle Group Only) (Safety Population)

Ocular Events	1.1 mJ/shot N = 4 n (%)	1.2 mJ/shot N = 2 n (%)	1.3 mJ/shot N = 1 n (%)	1.4 mJ/shot N = 4 n (%)	1.5 mJ/shot N = 7 n (%)	1.6 mJ/shot N = 9 n (%)	1.7 mJ/shot N = 39 n (%)	1.8 mJ/shot N = 26 n (%)	1.9 mJ/shot N = 4 n (%)	Total N = 96 n (%)
Serious Adverse Events	**—**	**—**	**—**	**—**	**—**	**—**	**—**	**1 (3.8%)**	**—**	**1 (1.0%)**
Acute optic neuropathy	—	—	—	—	—	—	—	1 (3.8%)	—	1 (1.0%)
Non-Serious Adverse Events	**1 (25.0%)**	**—**	**—**	**1 (25.0%)**	**1 (14.3%)**	**1 (11.1%)**	**—**	**1 (3.8%)**	**1 (25.0%)**	**6 (6.3%)**
Cataract progression	1 (25.0%)	—	—	—	—	1 (11.1%)	—	1 (3.8%)	—	3 (3.1%)
Conjunctivitis	—	—	—	1 (25.0%)	—	—	—	—	—	1 (1.0%)
Diabetic retinopathy	—	—	—	—	—	—	—	—	1 (25.0%)	1 (1.0%)
Elevated IOP	—	—	—	—	1 (14.3%)	—	—	—	—	1 (1.0%)
Foreign body sensation	—	—	—	1 (25.0%)	—	—	—	—	—	1 (1.0%)
Any adverse events	**1 Reports from 1 participant 25.0%**	**0 Reports from 0 participants 0.0%**	**0 Reports from 0 participants 0.0%**	**2 Reports from 1 participant 25.0%**	**1 Reports from 1 participant 14.3%**	**1 Reports from 1 participant 11.1%**	**0 Reports from 0 participants 0.0%**	**2 Reports from 2 participants 7.7%**	**1 Reports from 1 participant 25.0%**	**8 Reports from 7 participants 7.3%**

The counts (n) are the number of participants reported with the corresponding events. % = n / N x 100%.
Multiple events could be reported for the same participant.

IX. Conclusions

The Eagle device has the same intended use as the legally marketed predicate device identified in this premarket notification. The IFU statement differs from that of the predicate, but the differences do not change the intended use of the device. The technological characteristics of the Eagle device differ from those of the predicate device, but the differences do not raise new or different types of questions of safety or effectiveness. The results of the non-clinical performance testing demonstrate that the Eagle device functions as intended. The results of the clinical performance testing support an acceptable safety and effectiveness profile that supports a determination of substantial equivalence. The non-clinical and clinical performance testing demonstrate that the Eagle device is substantially equivalent to the predicate device.