August 10, 2026

Nova Eye, Inc.
Don Watton
Head of Global Operations
41316 Christy St.
Fremont, California 94538

Re: K253468
Trade/Device Name: Nova Eye iTrack™ 250A Canaloplasty Microcatheter (iTrack™ 250A)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: MPA, HMX
Dated: July 7, 2026
Received: July 8, 2026

Dear Don Watton:

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.	K253468

Please provide the device trade name(s).

Nova Eye iTrack™ 250A Canaloplasty Microcatheter (iTrack™ 250A)

Please provide your Indications for Use below.

The Nova Eye iTrack™ 250A is indicated for fluid infusion and aspiration during surgery.
The Nova Eye iTrack™ 250A is indicated for catheterization and viscodilation of Schlemm's canal to reduce intraocular pressure in adult patients with open angle glaucoma.

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
K253468

I. Submitter Information

510(k) Owner: Nova Eye, Inc.
41316 Christy St.
Fremont, CA 94538

Contact Person: Don Watton
dwatton@nova-eye.com
+61-417-865-044

Date Prepared: August 9, 2026

II. Device Name and Classification

Device Trade Name: Nova Eye iTrack™ 250A Canaloplasty Microcatheter

Common Name: Canaloplasty Microcatheter

Regulation Numbers (Product Code): 21 CFR 876.1500 (MPA), 21 CFR 886.4350 (HMX)

Device Classification: Class 2

III. Predicate Device

Predicate Device

- iTrack™ 250A Canaloplasty Microcatheter (Nova Eye, Inc.) (K080067)

IV. Device Description

The Nova Eye iTrack™ 250A Canaloplasty Microcatheter ("iTrack™ 250A") is a flexible microcatheter designed to allow atraumatic catheterization of spaces in the eye for infusion and aspiration of fluids during surgery. The device allows catheterization and viscodilation of Schlemm's canal to reduce intraocular pressure in adult patients with open angle glaucoma.

The microcatheter has a lumen with a proximal Luer connector through which fluids can be introduced and delivered to the microcatheter tip under the control of the surgeon. The microcatheter also has a fiber optic for surgical illumination and guidance. The illumination is readily visualized when the microcatheter is within Schlemm's canal, allowing the surgeon to control the placement of the microcatheter tip.

The device is provided sterile and is intended for single use. Refer to Figure 1 provides a photo of the iTrack™ 250A.

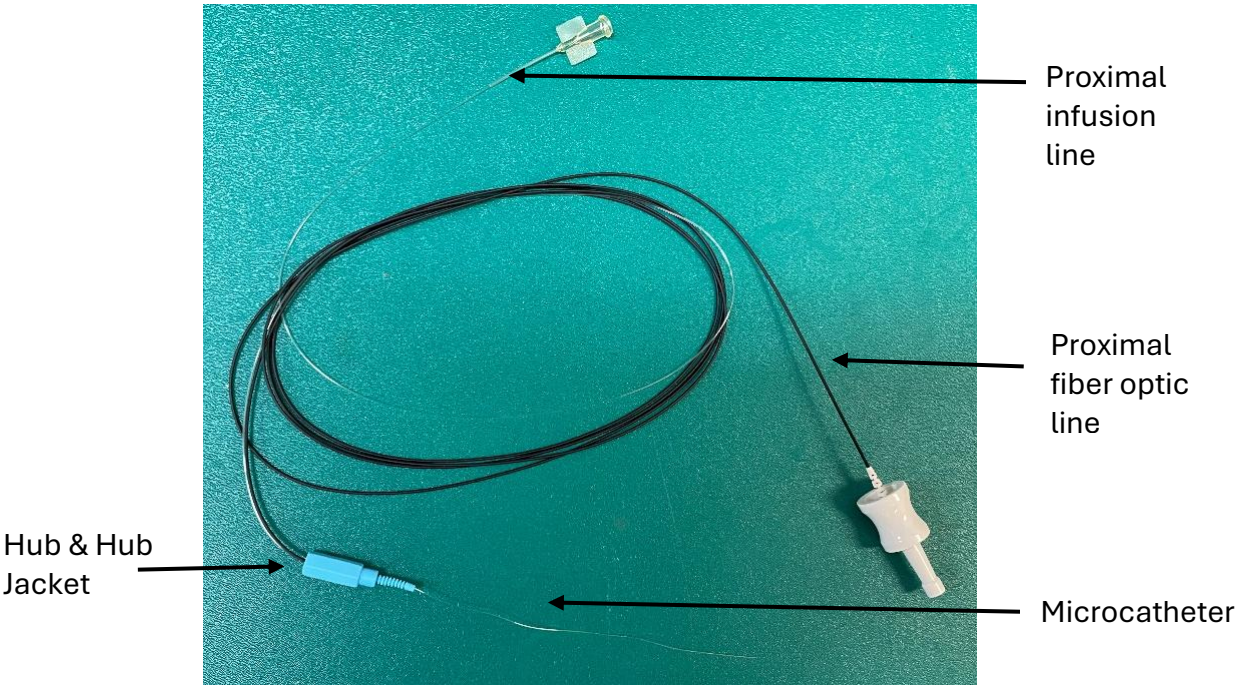

Figure 1: iTrack 250A Canaloplasty Microcatheter

V. Indications for Use

The Nova Eye iTrack™ 250A is indicated for fluid infusion and aspiration during surgery. The Nova Eye iTrack™ 250A is indicated for catheterization and viscodilation of Schlemm's canal to reduce intraocular pressure in adult patients with open angle glaucoma.

VI. Comparison of Technological Characteristics with the Predicate Devices

The subject iTrack™ 250A device and the predicate device share the same technological characteristics. The one difference in labeling between the subject and predicate devices does not raise different types of questions of safety and effectiveness.

Characteristic	Nova Eye iTrack™ 250A Canaloplasty Microcatheter SUBJECT DEVICE	Nova Eye iTrack™ 250A Canaloplasty Microcatheter (K080067) PREDICATE DEVICE	COMPARISON OF SUBJECT TO PREDICATE DEVICE
Intended Use	Delivery of controlled amounts of viscoelastic fluid during ophthalmic surgery, fluid infusion and aspiration, and catheterization and viscodilation (canaloplasty)	Delivery of controlled amounts of viscoelastic fluid during ophthalmic surgery, fluid infusion and aspiration, and catheterization and viscodilation (canaloplasty)	Same
Indications For Use	The Nova Eye iTrack™ 250A is indicated for fluid infusion and aspiration during surgery. The Nova Eye iTrack™ 250A is indicated for catheterization and viscodilation of Schlemm's canal (canaloplasty) to reduce intraocular pressure in adult patients with open-angle glaucoma.	The Nova Eye iTrack™ 250A is indicated for fluid infusion and aspiration during surgery. The Nova Eye iTrack™ 250A is indicated for catheterization and viscodilation of Schlemm's canal (canaloplasty) to reduce intraocular pressure in adult patients with open-angle glaucoma.	Same
Regulation	876.1500 (Endoscope and accessories) 886.4350 (Manual ophthalmic surgical instrument)	876.1500 (Endoscope and accessories) 886.4350 (Manual ophthalmic surgical inst rument)	Same
Device Class	Class II	Class II	Same
Product Code	MPA (Endoscope) HMX (Manual Ophthalmic Surgical Instrument)	MPA (Endoscope) HMX (Manual Ophthalmic Surgical Instrument)	Same
Prescription Status	Prescription use only	Prescription use only	Same
Target Anatomy	Schlemm's Canal	Schlemm's Canal	Same
Recommended Accessories	• Ophthalmic ViscoInjector™ (K050716) • iLumin™ Fiberoptic Illuminator (K062259)	• Ophthalmic ViscoInjector™ (K050716) • iLumin™ Fiberoptic Illuminator (K062259)	Same

Characteristic	Nova Eye iTrack™ 250A Canaloplasty Microcatheter SUBJECT DEVICE	Nova Eye iTrack™ 250A Canaloplasty Microcatheter (K080067) PREDICATE DEVICE	COMPARISON OF SUBJECT TO PREDICATE DEVICE
Viscoelastic Accessories	Viscoelastic is supplied separately by third-party manufacturers. Viscoelastic is delivered to/attaches to device via luer fitting.	Viscoelastic is supplied separately by third-party manufacturers. Viscoelastic is delivered to/attaches to device via luer fitting.	Same
Dispensing Control	Manual rotation of accessory ViscoInjector knob to dispense controlled amounts viscoelastic fluid	Manual rotation of accessory ViscoInjector knob to dispense controlled amounts viscoelastic fluid	Same
User Determines Amount of Fluid to Dispense	Yes, by rotating the proximal knob on the accessory ViscoInjector	Yes, by rotating the proximal knob on the accessory ViscoInjector	Same
Passive or Energized Device to Dispense Viscoelastic	Passive	Passive	Same
Volume Dispensed	2.25 µL per click of the accessory ViscoInjector	2.25 µL per click of the accessory ViscoInjector	Same
Dispensing Mechanism	Syringe volume exchange	Syringe volume exchange	Same
Operating Principle	Manual	Manual	Same
Surgical Approach	Labeling specifies *ab externo* and *ab interno* as being acceptable surgical approaches for accessing Schlemm's canal	Labeling specifies *ab externo* as being acceptable surgical approach for accessing Schlemm's canal	Different, but the difference does not raise different types of questions of safety and effectiveness. A systematic literature review was performed to characterize the safety and effectiveness of the subject device using an *ab interno* approach. Selected references from this systematic literature review were used to demonstrate the safety and effectiveness of the *ab interno*

Characteristic	Nova Eye iTrack™ 250A Canaloplasty Microcatheter SUBJECT DEVICE	Nova Eye iTrack™ 250A Canaloplasty Microcatheter (K080067) PREDICATE DEVICE	COMPARISON OF SUBJECT TO PREDICATE DEVICE
			approach to the iTrack™ 250A procedure to reduce IOP in adult patients.
Mechanism of Action	• The Microcatheter is connected to the accessory ViscoInjector™ and primed with viscoelastic fluid from a cartridge retained with the ViscoInjector. • The Microcatheter is connected to a powered iLumin™ Fiberoptic Illuminator which illuminates the Microcatheter tip. • The surgeon directs the microcatheter using micro forceps through the surgical incision into the ostium of the Schlemm's canal. • The Microcatheter can access 360° of Schlemm's canal in one pass. • As surgeon withdraws the microcatheter from the Schlemm's canal, viscoelastic fluid is delivered into the canal by the surgeon by manual clockwise rotation of the knob on ViscoInjector. • Clicks on the accessory ViscoInjector tactilely indicate precise delivery of viscoelastic fluid.	• The Microcatheter is connected to the accessory ViscoInjector™ and primed with viscoelastic fluid from a cartridge retained with the ViscoInjector. • The Microcatheter is connected to a powered iLumin™ Fiberoptic Illuminator which illuminates the Microcatheter tip. • The surgeon directs the microcatheter using micro forceps through the surgical incision into the ostium of the Schlemm's canal. • The Microcatheter can access 360° of Schlemm's canal in one pass. • As surgeon withdraws the microcatheter from the Schlemm's canal, viscoelastic fluid is delivered into the canal by the surgeon by manual clockwise rotation of the knob on ViscoInjector. • Clicks on the accessory ViscoInjector tactilely indicate precise delivery of viscoelastic fluid.	Same
Materials	Medical grade materials including: Polyimide, Polycarbonate, PEBAX, Stainless Steel, Polystyrene, PMMA, PVDF, Cyanoacrylate, Thermoplastic Elastomer	Medical grade materials including: Polyimide, Polycarbonate, PEBAX, Stainless Steel, Polystyrene, PMMA, PVDF, Cyanoacrylate, Grilamid	Similar
User Interface	Handheld	Handheld	Same

Characteristic	Nova Eye iTrack™ 250A Canaloplasty Microcatheter SUBJECT DEVICE	Nova Eye iTrack™ 250A Canaloplasty Microcatheter (K080067) PREDICATE DEVICE	COMPARISON OF SUBJECT TO PREDICATE DEVICE
Microcatheter Shaft Outer Diameter	200 microns	200 microns	Same
Microcatheter Tip Outer Diameter (nominal)	250 microns	250 microns	Same
Length of Distal Shaft of Microcatheter	45mm	45mm	Same
Sterile and Single Use	Provided sterile. Single patient use	Provided sterile. Single patient use	Same
Sterilization Method	Gamma radiation	Gamma radiation	Same
Sterility Assurance Level	10^{-6}	10^{-6}	Same
Packaging	Closed tray inside a sealed Tyvek pouch	Closed tray inside a sealed Tyvek pouch	Same
Shelf Life	2 years	2 years	Same

The Directions for Use for the iTrack 250A were updated to reflect that the procedure can be performed via an *ab interno* approach. This change does not raise new types of questions regarding the safety and effectiveness of the device.

In addition, minor changes were made to device since the previous 510(k) clearance which did not require a 510(k) notification. These minor changes included a change to an integrated control hub, minor changes to a luer material and microcatheter material, and updating a connector design.

VII. Summary of Non-Clinical Testing

No bench testing was performed to support this labeling change. Testing that was carried out to support minor changes was reviewed to support the substantial equivalence determination.

The following testing was performed to support the minor changes made to device since the previous 510(k) clearance which did not require a 510(k) notification:

- **Bench Testing:** Bench testing of the iTrack 250A included dimensional verification of several critical dimensions. Additionally, mechanical testing was performed in accordance with ISO 10555-1:2023 including tensile strength, burst pressure, line leakage and fluid infusion testing. Results demonstrated that the device met all applicable specifications and acceptance criteria.
- **Packaging Validation/Shelf Life:** Packaging validation and shelf-life studies were performed to validate the packaging and claimed shelf life. Packaging validation was conducted in accordance with ISO 11607-1:2019, ISO 11607-2:2019. Transit conditioning and distribution testing were conducted in accordance with ASTM D4332-22 and ASTM D4169-23. Aging studies were conducted in accordance with ASTM F1980-21. Package integrity, seal integrity, visual inspection, and label adhesion/legibility testing were performed, including seal strength testing in accordance with ASTM F88/F88M-23.
- **Sterilization Validation:** Sterilization validation was performed in accordance with ISO 11737-1:2018, ISO 11737-2:2019, ISO 11137-1:2006/Amd 2:2018 and ISO 11137-2:2013/Amd 1:2022. The iTrack 250A maintains a sterility assurance level of SAL $10^{-6.}$
- **Bacterial Endotoxin Testing:** Routine Endotoxin testing is performed on kits from this product family in accordance with FDA's 2015 Endotoxin Guidance, "Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices" and relevant portions of USP-NF Chapter <85> and USP-NF Chapter <161>. The kits conform to the established specification of ≤0.2 EU/device.
- **Biocompatibility Testing:** 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 10993-1 Biological Evaluation of Medical Devices standard series.

- **Light Hazard Testing:** A light hazard assessment was performed in accordance with ANSI Z80.36:2021 and ISO 15752:2010. The iTrack™ 250A is classified as a Group 1 device for light hazard.

VIII. Clinical Evidence

iTrack 250A results from the iTrack Global Data Registry (iTGDR)[1] were used to characterize the safety and effectiveness of *ab interno* iTrack 250A. The iTGDR is a prospective, multi-center, observational study of the iTrack 250A and iTrack Advance devices which recruited patients at 12 sites in the US, Australia, Germany and the United Kingdom. The study enrolled patients with glaucoma or ocular hypertension requiring canaloplasty to reduce IOP and/or medications, treated with iTrack 250A or iTrack Advance with or without concomitant cataract surgery, and a minimum of 12 months follow-up. Exclusion criteria included diagnosis of angle-closure glaucoma, iTrack surgery combined with other glaucoma surgery, and abnormalities of the angle (angle recession, neovascularization, peripheral anterior synechiae). Follow-up visits were performed at 1 day, 1 week, 1-, 3-, and 6- months and half-yearly follow-ups thereafter (12-, 18-, 24-, 30- months and so on).

In addition, three other publications from a systematic literature review were selected to characterize the effectiveness of *ab interno* iTrack™ 250A.

The combined safety data from the iTGDR and other selected studies were used to characterize the safety of *ab interno* iTrack™ 250A.

Effectiveness

Effectiveness data from a total of 241 eyes treated with *ab interno* iTrack™ 250A were obtained from one prospective study[1] and 3 retrospective studies.[2,3,4] Across the studies, an average of 85%-95% of eyes were diagnosed with POAG, the mean age of patients treated ranged from 70-75 years old, and approximately 50-60% were female, on average. One hundred sixty-six (166)

[1] Kerr N, Lubeck D, Barton K, Aref AA, Cheng J, Spaulding J, Shoham-Hazon N, Thomsen S, Patel S, Harasymowycz P, Singh H, Mercieca K, Ahmed IIK. A Prospective, Real-World, Multicenter Study to Support the Role of Ab-Interno Canaloplasty in Glaucoma Management. Am J Ophthalmol. 2026 Apr;284:235-246.

[2] Gallardo MJ, Supnet RA, Ahmed II. Viscodilation of Schlemm's canal for the reduction of IOP via an ab-interno approach. Clin Ophthalmol. 2018 Oct 23:2149-55

[3] Gillmann K, Aref A, Niegowski LJ, Baumgartner JM. Combined *ab interno* viscocanaloplasty (ABiC) in open-angle glaucoma: 12-month outcomes. Int Ophthalmol. 2021 Oct;41(10):3295-301.

[4] Khaimi MA, Koerber N, Ondrejka S, Gallardo MJ. Consistency in standalone canaloplasty outcomes using the iTrack microcatheter. Clin Ophthalmol. 2024 Dec 31;18:173-83.

eyes were treated with *ab interno* iTrack™ 250A in combination with cataract surgery, and 75 were treated with *ab interno* iTrack™ 250A alone.

Table 1 below summarizes the IOP over time across the studies, stratified by the type of procedure performed (combo vs. standalone). This summary shows that the average baseline IOP for the *ab interno* iTrack™ 250A studies ranged from 19.4 – 23.6 mmHg. The average IOP at 12 months ranged from 13.0 – 19.8 mmHg. For **combo surgery**, the mean reduction in IOP at 12 months was reported to range from -6.4 to -9.4 mmHg. For **standalone surgery**, the mean reduction in IOP at 12 months ranged from -4.9 to -7.9 mmHg.

Table 1: Summary of Change in IOP, Stratified by Type of Procedure Performed

Combo			
Source	Kerr[1,5]	Gallardo[2]	Gillman[3]
N eyes	78	34	54
Baseline IOP (mmHg) (Mean ± SD)	22.7 ± 5.0	19.41[6]	23.6 ± 7.4
12 Month IOP (mmHg) (Mean ± SD)	15.2 ± 3.6	12.97[6]	14.2 ± 2.9
Mean Absolute IOP Reduction from BL (mmHg)[7]	**-7.5**	**-6.4**	**-9.4**
% of Eyes with ≥ 20% IOP Reduction at 1 Year Compared to BL	78.9% (56/71)	88.2% (30/34)	NR
% of Eyes with ≥ 20% IOP Reduction at 1 Year Compared to BL and Medication Free	NR	NR	46% (25/54)
Stand-Alone			
Source	Kerr[1]	Khaimi[4]	
N eyes	11	64	
Baseline IOP (mmHg) (Mean ± SD)	24.6 ± 4.7	22.9 ± 7.03	
12 Month IOP (mmHg) (Mean ± SD)	19.8 ± 7.6	15.0 ± 2.90	
Mean Absolute IOP Reduction from BL (mmHg)[7]	**-4.9**	**-7.9**	
% of Eyes with ≥ 20% IOP Reduction at 1 Year Compared to BL	37.5% (3/8)	77.6% (45/64)	

NR: Not reported

Table 2 summarizes the number of glaucoma medications used over time. For **combo surgery**, the mean reduction in glaucoma medications at 12 months ranged from -0.7 to -2.3

[5] Data for the subgroup of iTrack 250A eyes with higher baseline IOP (IOP > 18 mmHg) are presented.
[6] Standard deviation not reported for the combo sub-group.
[7] If mean reduction was not reported in the publication, it was approximated by final IOP – baseline IOP.

medications. For **standalone surgery**, the mean reduction in glaucoma medications at 12 months ranged from -1.1 to -1.6 meds.

Table 2: Summary of Change in Glaucoma Medication Use, Stratified by Type of Procedure Performed

Combo			
Source	Kerr	Gallardo	Gillman
N eyes	78	34	54
# Meds at Baseline (BL) (Mean ± SD)	1.9 ± 1.2	2.59	2.9 ± 1.0
# Meds at 12 Mo (Mean ± SD)	1.1 ± 1.3	0.85	0.6 ± 1.1
Mean Medication Reduction from BL	**-0.7**	**-1.74**	**-2.3**
Stand-Alone			
Source	Kerr	Khaimi	
N eyes	11	64	
# Meds at Baseline (BL) (Mean ± SD)	2.4 ± 0.9	2.78 ± 0.83	
# Meds at 12 Mo (Mean ± SD)	1.3 ± 1.5	1.14 ± 1.12	
Mean Medication Reduction from BL	**-1.1**	**-1.64**	

Safety

Table 3 presents the safety data for *ab interno* iTrack™ 250A. To provide the most comprehensive analysis of safety data for the *ab interno* iTrack™ 250A, safety data are presented separately for all relevant studies (n=12). Adverse event data from a total of 668 eyes treated with *ab interno* iTrack™ 250A are presented.[8] The publications from which the safety data were compiled had a follow-up range from 12 months to 6 years.

The most common adverse events reported were IOP elevation (n=68 eyes), CDVA loss of ≥ 2 lines (n=19 eyes), choroidal effusion (n=27 eyes), and hyphema (n=29 eyes). All others adverse events were reported in < 2.0% of eyes. A total of 34 secondary surgical interventions were reported.

The rate of CDVA loss of ≥ 2 lines was reported in one study[1] which had longer mean follow-up duration of 22 months. Visual acuity loss in this study was most commonly attributed to pre-

[8] One study evaluated rates of postoperative endophthalmitis for *ab interno* canaloplasty with iTrack 250A and reported 1 case out of 3256 eyes (0.03%). No eye which underwent standalone *ab interno* canaloplasty (n = 1332) experienced postoperative endophthalmitis, while 1 eye which had *ab interno* canaloplasty combined with cataract surgery (n = 1924) did. Given the large number of eyes and the exclusive focus on endophthalmitis, data from this report was only included in the rate of endophthalmitis.

existing advanced disease or unrelated ocular comorbidities. BCVA loss of ≥ 2 lines in the other studies was reported in a combined total of 5 eyes.

The varying rate of occurrence of IOP elevation may be due in part to varying definitions of IOP elevation across studies – some defined it as ≥ 10 mmHg above baseline and others defined it as IOP ≥ 30 mmHg.

All the reported choroidal effusions (n=27 eyes) were from one study reported by Yin, et al.[9] Yin, et al performed anterior segment swept-source OCT (AS-OCT) at each follow-up visit to identify and monitor supraciliary effusion. Using this imaging method, they reported that supraciliary effusion occurred at a rate of 71% (27/38) for the *ab interno* iTrack™ 250A group and 92% for their comparator gonioscopy-assisted transluminal trabeculotomy (GATT) group. Given the high rate of choroidal effusion reported in this study for both treatment groups, and that fact that no other studies reported this event, it seems likely that the OCT imaging performed in this study detected sub-clinical findings and the rate of clinically relevant choroidal effusion for *ab interno* iTrack™ 250A is much lower.

The definition for reporting hyphema was not uniform across all studies. In addition, the Yin, et al study reported that hyphema, almost all of which absorbed within 1 week, occurred at a high rate of 47% (18/38) for *ab interno* iTrack 250A group and 87% for its comparator GATT group.

[9] Yin P, Li J, Shi Y, Cao K, Han Y, Wang H et al. *Ab interno* canaloplasty versus gonioscopy-assisted transluminal trabeculotomy in open-angle glaucoma: a randomised controlled trial. Br J Ophthalmol. 2024 May 1;108(5):687-94.

Table 3: Safety Data for *ab interno* iTrack 250A

	Kerr 2026[1]	Gallardo 2018[10]	Gallardo 2018[2] Gallardo 2022[11]	Gillmann 2021[3]	Kazerounian 2020[12]	Khaimi 2021[13]	Khaimi 2024[4]	Khan 2022[14]	Kicińska 2022[15] Kicińska 2023[16]	Koerber 2024[17] Koerber 2022[18]	Koerber 2018[19]	Patel 2023[20]	Yin 2023[9]
N eyes *ab interno* iTrack 250A	256	12	81	54	25	45	22[21]	3256	16	27	20	72	38
Anterior chamber inflammation	1 (0.4%)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Aqueous misdirection[22]	1 (0.4%)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
BCVA loss of ≥ 2 lines Snellen	NR	NR	4/75 (5.3%)[23]	0 (0%)	NR	NR	0 (0%)	NR	0 (0%)	NR	NR	NR	1 (2.6%)[24]

[10] Gallardo MJ, Supnet RA, Ahmed II. Circumferential viscodilation of Schlemm's canal for open-angle glaucoma: ab-interno vs ab-externo canaloplasty with tensioning suture. Clin Ophthalmol. 2018 Dec 5:2493-98.
[11] Gallardo MJ. 36-month effectiveness of ab-interno canaloplasty standalone versus combined with cataract surgery for the treatment of open-angle glaucoma. Ophthalmol Glaucoma. 2022 Sep 1;5(5):476-82.
[12] Kazerounian S, Zimbelmann M, Lörtscher M, Hommayda S, Tsirkinidou I, Müller M. Canaloplasty ab interno (AbiC) - 2-year-results of a novel minimally invasive glaucoma surgery (MIGS) technique. Klin Monbl Augenheilkd. 2021 Oct;238(10):1113-1119.
[13] Khaimi MA. Long-term medication reduction in controlled glaucoma with iTrack ab-interno canaloplasty as a standalone procedure and combined with cataract surgery. Ther Adv Ophthalmol. 2021 Sep;13:25158414211045751.
[14] Khan A, Riaz KM, Rangu N, Shah VA, Hussain ZS, Khaimi MA. Incidence and clinical characteristics of postoperative endophthalmitis after ab-interno canaloplasty. Clin Ophthalmol. 2022 Nov 22;16:3875.
[15] Kicińska AK, Danielewska ME, Rękas M. Safety and Efficacy of Three Variants of Canaloplasty with Phacoemulsification to Treat Open-Angle Glaucoma and Cataract: 12-Month Follow-Up. J Clin Med. 2022 Nov 2;11(21):6501.
[16] Kicińska AK, Rękas M. Safety and efficacy of three modifications of canaloplasty to treat open-angle glaucoma: 3-year outcomes. J Clin Med. 2023 Oct 11;12(20):6475.
[17] Koerber N, Ondrejka S. 6-year efficacy and safety of iTrack ab-interno canaloplasty as a stand-alone procedure and combined with cataract surgery in primary open angle and pseudoexfoliative glaucoma. J Glaucoma. 2024 Mar 1;33(3):176-82.
[18] Koerber N, Ondrejka S. Four-Year Efficacy and Safety of iTrack Ab-interno Canaloplasty as a Standalone Procedure and Combined with Cataract Surgery in Open-Angle Glaucoma. Klin Monbl Augenheilkd. 2023 Dec;240(12):1394-1404.
[19] Körber N. Ab interno canaloplasty for the treatment of glaucoma: a case series study. Spektrum Augenheilkd. 2018 Dec;32(6):223-7.
[20] Patel S, Reiss G. Long-term clinical and safety outcomes of canaloplasty performed across all grades of glaucoma severity. J Ophthalmol. 2023;2023(1):5625990.
[21] While 64 eyes were treated in this study, only the 22 eyes unique to this study (i.e., no overlap with Gallardo 2022 or Koerber 2022 cohorts) are reported.
[22] This event occurred in an eye undergoing combined cataract extraction and canaloplasty and is not specific to the canaloplasty procedure.
[23] When 2 eyes were treated, BCVA loss was only reported for the 75 first-enrolled eyes reported in Gallardo 2022 so as to only include 1 eye per subject; all 4 cases of BCVA loss were attributed to ocular surface disease.
[24] BCVA loss noted to be due to crystalline lens opacity.

	Kerr 2026[1]	Gallardo 2018[10]	Gallardo 2018[2] Gallardo 2022[11]	Gillmann 2021[3]	Kazerounian 2020[12]	Khaimi 2021[13]	Khaimi 2024[4]	Khan 2022[14]	Kicińska 2022[15] Kicińska 2023[16]	Koerber 2024[17] Koerber 2022[18]	Koerber 2018[19]	Patel 2023[20]	Yin 2023[9]
CDVA loss of ≥ 2 lines Snellen[25]	19 (7.4%)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Cataract Surgery within 12 M postop	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0 (0%)
Choroidal Detachment	NR	NR	NR	NR	NR	NR	NR	NR	0 (0%)	0 (0%)	NR	NR	0 (0%)
Choroidal (Supraciliary) Effusion	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	27 (71.1%)[26]
Corneal Decompensation	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0 (0%)
Corneal Erosion	NR	NR	NR	NR	NR	NR	NR	NR	1 (6.3%)	NR	NR	NR	NR
Cystoid Macular Edema	1 (0.4%)	NR	NR	NR	NR	NR	NR	NR	0 (0%)	NR	NR	NR	NR
Descemet Membrane Detachment	1 (0.4%)	NR	NR	2 (3.7%)	1 (4.0%)[27]	NR	NR	NR	NR	1 (3.7%)	1 (5.0%)	1 (1.4%)	NR
Descemet Folds, Transient	NR	NR	NR	NR	NR	NR	NR	NR	6 (37.5%)	NR	NR	NR	NR
Endophthalmitis	NR	NR	NR	NR	NR	NR	NR	1 (0.03%)	NR	NR	NR	NR	NR
Endothelial Blood Stain	NR	NR	NR	1 (1.9%)	NR	NR	NR	NR	NR	NR	NR	NR	NR
Fibrin Plug	NR	NR	NR	1 (1.9%)	NR	NR	NR	NR	NR	NR	NR	NR	NR
Hyphema	4 (1.6%)	NR	3 (3.7%)	NR	3 (12.0%)	0	0	NR	1 (6.3%)	NR	0 (0%)	NR	18 (47.4%)[26]
Hypotony	NR	NR	NR	0 (0%)	NR	NR	NR	NR	0 (0%)	NR	NR	NR	0 (0%)
IOL Subluxation	NR	NR	NR	1 (1.9%)	NR	NR	NR	NR	NR	NR	NR	NR	NR
Iris Atrophy	NR	NR	NR	1 (1.9%)	NR	NR	NR	NR	NR	NR	NR	NR	NR
Iris Trauma	NR	NR	NR	1 (1.9%)	NR	NR	NR	NR	NR	NR	NR	NR	NR

[25] Mean follow-up duration for this study was 22.2±7.9 months.
[26] Refer to discussion in Safety section.
[27] Noted as a localized crescent-shaped elevation close to the limbus, which resolved spontaneously over 4 weeks.

	Kerr 2026[1]	Gallardo 2018[10]	Gallardo 2018[2] Gallardo 2022[11]	Gillmann 2021[3]	Kazerounian 2020[12]	Khaimi 2021[13]	Khaimi 2024[4]	Khan 2022[14]	Kicińska 2022[15] Kicińska 2023[16]	Koerber 2024[17] Koerber 2022[18]	Koerber 2018[19]	Patel 2023[20]	Yin 2023[9]
IOP Elevation ≤30 days post-op													
Elevation ≥ 10 mmHg above baseline IOP	35/234 (15.0%)	0 (0%)	3 (3.7%)	12 (22.2%)	NR	NR	NR	NR	NR	NR	NR	NR	NR
IOP >30 mmHg	27/234 (11.5%)	NR	NR	NR	NR	NR	NR	NR	2 (12.5%)[28]	NR	NR	NR	16 (42.1%)[28]
Posterior Capsular Rupture	NR	NR	NR	1 (1.9%)	NR	NR	NR	NR	NR	NR	NR	NR	NR
Pupillary Block	NR	NR	NR	1 (1.9%)	NR	NR	NR	NR	NR	NR	NR	NR	NR
Retinal Detachment	1 (0.4%)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Secondary Surgical Interventions (SSI)													
Overall SSI	12 (4.7%)	NR	4 (4.9%)	7 (13.0%)	3 (12.0%)	NR	4 (18.2%)	NR	0 (0%)	1 (3.7%)	NR	NR	3 (7.9%)
Ab Externo Canaloplasty	1 (0.4%)	NR	NR	NR	3 (12.0%)	NR	NR	NR	NR	NR	NR	NR	NR
Cyclophotocoagulation	2 (0.8%)	NR	NR	NR	NR	NR	1 (4.5%)	NR	NR	NR	NR	NR	NR
ExPress Shunt	1 (0.4%)	NR	2 (2.5%)	NR	NR	NR	3 (13.6%)	NR	NR	NR	NR	NR	NR
Glaucoma Drainage Device	2 (0.8%)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
iStent	NR	NR	NR	NR	NR	NR	NR	NR	NR	1 (3.7%)[29]	NR	NR	NR
Preserlo Microshunt	1 (0.4%)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Selective Laser Trabeculoplasty	4 (1.6%)	NR	1 (1.2%)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Trabeculectomy	1 (0.4%)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
XEN Gel Stent	NR	NR	1 (1.2%)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Unspecified Glaucoma Surgery	NR	NR	NR	7 (13.0%)	NR	NR	NR	NR	NR	NR	NR	NR	3 (7.9%)

NR = None reported

[28] Definition used by Kicinska and Yin was ≥30 mmHg.

[29] At 5 years postoperative.

This analysis of data from the literature showed that *ab interno* iTrack™ 250A provided a clinically meaningful reduction in IOP at 12 months, for both combo and standalone surgery. The types of adverse events reported for *ab interno* iTrack™ 250A are similar to that reported for other canal-based *ab interno* glaucoma procedures and the rates of these events were acceptable. These data demonstrate the safety and effectiveness of *ab interno* iTrack™ 250A for lowering intraocular pressure in patients with open angle glaucoma.

IX. Conclusions

The design of the iTrack™ 250A is identical to the design of the Predicate device. In addition, the iTrack™ 250A maintains the same intended use, indications, target population, target anatomy, principle of operation, mechanism of action, and key technological characteristics as the Predicate device. All devices are manually operated and utilize a microcatheter with an illuminated tip to access Schlemm's canal and deliver viscoelastic fluid. The modification to the product labeling of the subject device, specifying both *ab externo* and *ab interno* as being acceptable surgical approaches for accessing Schlemm's canal, does not raise different types of questions of safety or effectiveness.

Ab interno iTrack 250A clinical performance data from the iTGDR registry as well as data from other *ab interno* publications from the systematic literature review demonstrate that the clinical performance data for *ab interno* iTrack™ 250A is substantially equivalent to that of the predicate *ab externo* iTrack™ 250A device.