May 29, 2026

Interojo, Inc.
Bret Andre
Official Correspondent
Andre Vision and Device Research
6119 Canter Ln.
West Linn, OR 97068

Re: K260507
Trade/Device Name: Interojo 45 (inofilcon A) Soft (hydrophilic) Silicone Hydrogel Contact Lens with GrabSoo Plus
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: February 12, 2026
Received: April 28, 2026

Dear Bret Andre:

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,

J Angelo Green -S

J. Angelo Green, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K260507

Device Name

Interojo 45 (inofilcon A) Soft (Hydrophilic) Silicone Hydrogel Contact Lens with GrabSoo Plus

Indications for Use *(Describe)*

The Interojo 45 (inofilcon A) Soft (Hydrophilic) Silicone Hydrogel Contact Lens with GrabSoo Plus is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 0.75 diopters or less, that does not interfere with visual acuity. The daily wear lens may be prescribed for monthly replacement in powers ranging from +15.00D to -20.00D.

The Interojo 45 (inofilcon A) Soft (Hydrophilic) Silicone Hydrogel Contact Lens with GrabSoo Plus for Astigmatism is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of up to 4.00 diopters, that does not interfere with visual acuity. The daily wear lens may be prescribed for monthly replacement in powers ranging from +6.00D to -12.00D.

The Interojo 45 (inofilcon A) Soft (Hydrophilic) Silicone Hydrogel Contact Lens with GrabSoo Plus for Presbyopia is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) and presbyopia in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 0.75 diopters or less, that does not interfere with visual acuity. The daily wear lens may be prescribed for monthly replacement in a power range of +6.00 to -12.00 diopters with add power ranging from +1.00D to +4.00D.

The Interojo 45 (inofilcon A) Soft (Hydrophilic) Silicone Hydrogel Contact Lens with GrabSoo Plus is to be cleaned, rinsed and disinfected each time it is removed from the patient's eye. The lens may be disinfected using a chemical disinfection system and should be discarded after one month of use or according to the recommended wearing period prescribed by the eye care practitioner.

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.

K260507

510 (k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K260507

I. SUBMITTER

Date Prepared: February 9, 2026

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II. DEVICE

Trade Name: **Interojo 45 (inofilcon A) Soft (Hydrophilic) Silicone Hydrogel Contact Lens with GrabSoo Plus**

Common Name: lenses, soft contact, daily wear

Classification Name: Soft (hydrophilic) Contact Lens (21 CFR 886.5925)

Regulatory Class: Class II

Product Codes: LPL

Purpose of 510(k) Submission:

~ New Device ~

III. PREDICATE DEVICE

The **Interojo 45 (inofilcon A) Soft (Hydrophilic) Silicone Hydrogel Contact Lens with GrabSoo Plus** is substantially equivalent to the following predicate devices:

- **"BAUSCH + LOMB ULTRA (samfilcon A) Contact Lenses"**
  By BAUSCH & LOMB INCORPORATED
  510(k) number; **K131208**
  Product Code: LPL; MVN
  Primary Predicate

IV. DEVICE DESCRIPTION

The **Interojo 45 (inofilcon A) Soft (Hydrophilic) Silicone Hydrogel Contact Lens with GrabSoo Plus** is a fully molded soft contact lens designed with hydrophilic properties that facilitate the absorption of aqueous solutions. Manufactured from inofilcon A—a silicone hydrogel material combined with other hydrophilic monomers—the lens comprises 55.0% inofilcon A and 45.0% water by weight when saturated in saline solution. The designation 'inofilcon A' has been adopted by the United States Adopted Names Council (USAN).

The **Interojo 45 (inofilcon A) Soft (Hydrophilic) Silicone Hydrogel Contact Lens with GrabSoo Plus** contains Reactive Blue 246 (21 CFR Part 73.3106) for visibility and handling. The **Interojo 45 (inofilcon A) Soft (Hydrophilic) Silicone Hydrogel Contact Lens with GrabSoo Plus** incorporates a UV absorbing monomer to help protect against transmission of harmful UV radiation. The lens absorbs >99.05% in the UVB range (280nm - 315nm), and >90.5% in the UVA range (315nm - 380nm).

The material properties and available parameters of the finished lenses are as follows:

Parameter	Range	Tolerance*
Chord Diameter	13.70 mm to 14.50 mm	±0.20 mm
Center Thickness	0.068 mm to 0.508 mm	When ≤ 0.10 mm → ±0.010 mm + 10% When > 0.10 mm → ±0.015 mm + 5%
Base Curve	8.00 mm to 9.40 mm	±0.20 mm
Back Vertex Power (F'v)	+15.00 D to -20.00D (in 0.25D steps)	When 0.00 < |F'v| ≤ 10.00 D → ±0.25 D When 10.00 < |F'v| ≤ 20.00 D → ±0.50 D
Cylinder Power (F'c)	0.00 D to -4.00 D (in 0.25 D steps)	When 0.00 < |F'c| ≤ 2.00 D → ±0.25 D When 2.00 < |F'c| ≤4.00 D→±0.37 D
Cylinder Axis	10° to 180° in 10° steps (in 10° steps)	± 5°
Multifocal Power	+1.00 D to +4.00 D (in 0.25 D steps)	±0.25D
Surface Appearance	-	Lenses should be clear with no surface defect
Oxygen Permeability (x 10^{-11}(cm^2/sec)(mlO_2)/(ml x mmHg))	70	±20%
Light Transmission - Tinted (@ 380-780nm)	95%	±5%
Ultraviolet (UV) Light Transmission	@280~315 nm: Avg 0.95% @315~380 nm: Avg 9.5%	-
Water Content	45%	±2%
Refractive Index	1.403 (hydrated)	±0.005

* ISO 18369-2:2017 Ophthalmic optics — Contact lenses — Part 2: Tolerances

V. INDICATIONS FOR USE

The **Interojo 45 (inofilcon A) Soft (Hydrophilic) Silicone Hydrogel Contact Lens with GrabSoo Plus** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 0.75 diopters or less, that does not interfere with visual acuity. The daily wear lens may be prescribed for monthly replacement in powers ranging from +15.00D to -20.00D.

The **Interojo 45 (inofilcon A) Soft (Hydrophilic) Silicone Hydrogel Contact Lens with GrabSoo Plus for Astigmatism** is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of up to 4.00 diopters, that does not interfere with visual acuity. The daily wear lens may be prescribed for monthly replacement in powers ranging from +6.00D to -12.00D.

The **Interojo 45 (inofilcon A) Soft (Hydrophilic) Silicone Hydrogel Contact Lens with GrabSoo Plus for Presbyopia** is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) and presbyopia in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 0.75 diopters or less, that does not interfere with visual acuity. The daily wear lens may be prescribed for monthly replacement in a power range of +6.00 to -12.00 diopters with add power ranging from +1.00D to +4.00D.

The **Interojo 45 (inofilcon A) Soft (Hydrophilic) Silicone Hydrogel Contact Lens with GrabSoo Plus** is to be cleaned, rinsed and disinfected each time it is removed from the patient's eye. The lens may be disinfected using a chemical disinfection system and should be discarded after one month of use or according to the recommended wearing period prescribed by the eye care practitioner.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The **Interojo 45 (inofilcon A) Soft (Hydrophilic) Silicone Hydrogel Contact Lens with GrabSoo Plus** is substantially equivalent to the primary predicate device identified (K131208) with regards to the following features:

- FDA category - Group V
- FDA classification – Class II, Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
- FDA product code – LPL
- Intended use – Daily wear soft contact lenses
- Indications for use
- Injection molded blister packaging
- Handling tint (Reactive Blue 246)

The following matrix illustrates the production method, lens function and material characteristics of the **Interojo 45 (inofilcon A) Soft (Hydrophilic) Silicone Hydrogel Contact Lens with GrabSoo Plus**, as well as the predicate device.

	Interojo 45 (inofilcon A) By Interojo Inc.	**BAUSCH + LOMB ULTRA (samfilcon A) Contact Lenses By Bausch & Lomb Incorporated**
	Subject Device	**Primary Predicate (K131208)**
Intended Use	Daily wear, Soft (hydrophilic) contact lens	Daily wear, Soft (hydrophilic) contact lens
Actions	In its hydrated state, the contact lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina	In its hydrated state, the contact lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina
FDA Classification	Soft (hydrophilic) Contact Lens (21 CFR 886.5925)	Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
Product Code(s)	LPL	LPL, MVN
FDA Group	FDA Group V	FDA Group V
USAN name	inofilcon A	samfilcon A
Water Content (%)	45±2%	46±2%
Oxygen Permeability x 10^{-11} (cm^2/sec)(mlO_2)/(ml x mmHg @ 35°C))	70	114
Refractive Index (wet)	1.403	1.411
UV Absorber	Yes	No
Manufacturing	Fully-Molded	Fully-Molded
Color	Reactive Blue 246	Reactive Blue 246
Blister Packaging	Yes	Yes

The following matrix compares the indications for use of the **Interojo 45 (inofilcon A) Soft (Hydrophilic) Silicone Hydrogel Contact Lens with GrabSoo Plus** with the predicate device.

	Indications for Use
Interojo 45 (inofilcon A) by Interojo Inc. (Subject Device)	The Interojo 45 (inofilcon A) Soft (Hydrophilic) Silicone Hydrogel Contact Lens with GrabSoo Plus is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 0.75 diopters or less, that does not interfere with visual acuity. The daily wear lens may be prescribed for monthly replacement in powers ranging from +15.00D to -20.00D. The Interojo 45 (inofilcon A) Soft (Hydrophilic) Silicone Hydrogel Contact Lens with GrabSoo Plus for Astigmatism is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of up to 4.00 diopters, that does not interfere with visual acuity. The daily wear lens may be prescribed for monthly replacement in powers ranging from +6.00D to -12.00D. The Interojo 45 (inofilcon A) Soft (Hydrophilic) Silicone Hydrogel Contact Lens with GrabSoo Plus for Presbyopia is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) and presbyopia in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 0.75 diopters or less, that does not interfere with visual acuity. The daily wear lens may be prescribed for monthly replacement in a power range of +6.00 to -12.00 diopters with add power ranging from +1.00D to +4.00D. The Interojo 45 (inofilcon A) Soft (Hydrophilic) Silicone Hydrogel Contact Lens with GrabSoo Plus is to be cleaned, rinsed and disinfected each time it is removed from the patient's eye. The lens may be disinfected using a chemical disinfection system and should be discarded after one month of use or according to the recommended wearing period prescribed by the eye care practitioner.
Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens by Bausch & Lomb Incorporated (K131208)	The Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed for Frequent/Planned Replacement Wear or Disposable Wear in spherical powers ranging from +20.00D to -20.00D. The Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens for Astigmatism is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of up to 5.00 diopters, that does not interfere with visual acuity. The lens may be prescribed for Frequent/Planned Replacement Wear or Disposable Wear in spherical powers ranging from +20.00D to -20.00D. The Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens for Presbyopia is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) and presbyopia in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed for Frequent/Planned Replacement Wear or Disposable Wear in a power range of +20.00 to -20.00 diopters with add power ranging from +0.75D to +5.00D. FREQUENT/PLANNED REPLACEMENT WEAR When prescribed for Frequent/Planned Replacement Wear, the Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens, Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens for Astigmatism, and Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens for Presbyopia is to be cleaned, rinsed and disinfected each time it is removed from the patient's eye and discarded after the recommended wearing period prescribed by the eye care practitioner. The lens may be disinfected using a chemical disinfection system. DISPOSABLE WEAR When prescribed for Disposable Wear, the Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens, Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens for Astigmatism, and Bausch + Lomb (samfilcon A) Soft (hydrophilic) Contact Lens for Presbyopia is to be discarded after each removal.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Non-Clinical Performance Testing

A series of non-clinical performance tests were conducted to show that the **Interojo 45 (inofilcon A) Soft (Hydrophilic) Silicone Hydrogel Contact Lens with GrabSoo Plus** is safe and effective. The findings indicate that this lens is substantially equivalent to similar devices already on the market. Below is a summary of the results from these non-clinical studies.

Toxicology:

Testing was conducted to assess the biocompatibility of the finished lenses, primary packaging materials, and primary packaging solution. All biocompatibility/toxicology tests were conducted in accordance with the GLP regulation.

- In-Vitro Cytotoxicity: Cytotoxicity testing was performed in accordance with ISO 10993-5 with results indicating that the finished lenses, primary packaging materials, and primary packaging solution are not cytotoxic.
- Systemic Toxicity: The extracts from the finished lenses and extracts from the primary packaging materials meet the requirements of the systemic injection test in accordance with ISO 10993-11 and do not produce acute systemic toxicity.
- Acute Ocular Irritation: Acute ocular irritation testing was performed in accordance with ISO 10993-23, and the extracts from finished lenses, extracts from the primary packaging materials, and the primary packaging solution produced no ocular irritation.
- Skin Sensitization Study (Maximization Test): The skin sensitization study was conducted in accordance with ISO 10993-10, and the contact lens extracts and primary packaging solution did not produce skin sensitization.
- 22-Day Ocular Irritation: The 22-day ocular irritation test was conducted in accordance with ISO 9394, and the finished contact lenses produced no ocular irritation.

Shelf Life:

Testing was performed to evaluate the stability, sterility, and package integrity of the **Interojo 45 (inofilcon A) Soft (Hydrophilic) Silicone Hydrogel Contact Lens with GrabSoo Plus** over the duration of the labeled expiration date. The data presented supports establishment of the shelf life.

Performance Testing - Bench:

Bench tests conducted include refractive index, water content, Dk, % transmission (visible & UV), tensile strength, modulus, % elongation to break, specific gravity, contact angle, and polymerization residuals. The results show that the **Interojo 45 (inofilcon A) Soft (Hydrophilic) Silicone Hydrogel Contac**t Lens with GrabSoo Plus has material properties consistent with predicate devices.

Solution Compatibility

The physical compatibility of **Interojo 45 (inofilcon A) Soft (Hydrophilic) Silicone Hydrogel Contact Lens with GrabSoo Plus** with commonly available cleaning and disinfection solutions (peroxide and MPDS) was confirmed following the methodology described in ISO 11981:2017, Ophthalmic optics - Contact lenses and contact lens care products - Determination of physical compatibility of contact lens care products with contact lenses.

Preservative Uptake and Release

Interojo 45 (inofilcon A) Soft (Hydrophilic) Silicone Hydrogel Contact Lenses with GrabSoo Plus were evaluated for preservative uptake and release consistent with those present in lens care solutions. The assessment was conducted in accordance with ISO 11986:2017, Ophthalmic optics - Contact lenses and contact lens care products - Determination of preservative uptake and release. Results indicate that the uptake **and releas**e profiles of inofilcon A contact lenses exhibited preservative levels below the detection limit at all time points assessed.

Clinical Testing

A three-month, open-label, randomized, bilateral, parallel-group study designed to evaluate and compare the safety and efficacy of the Interojo 45 Silicone Hydrogel Contact Lens for daily wear against the commercially available BAUSCH + LOMB ULTRA (samfilcon A) Contact Lenses (FDA clearance K131208) was conducted. Subjects meeting inclusion criteria underwent baseline assessments and lens fitting procedures prior to randomization. The total enrollment across all sites was 75 subjects (150 eyes) with 50 subjects (100 eyes) in the test group and 25 subjects (50 eyes) in the control group. The study cohort had a female-to-male ratio of 1:0.44 (52 females and 23 males). The mean age of participants was 29.48 years overall, with the test group averaging 28.18 years and the control group averaging 32.08 years. Of the 75 subjects enrolled, 69 subjects completed the scheduled visits (48 subjects in the test group and 21 subjects in the control group).

No serious adverse events were reported throughout the duration of the study. In the test group, a single non-device-related ocular adverse event was recorded. Device-related ocular adverse events classified as significant but non-serious were observed in a total of six eyes across four subjects. Specifically, in the control group, four eyes required clinical intervention: two cases of conjunctival injection detected by slit lamp examination and two cases of ocular pain/lens sensitivity identified through patient-reported symptoms. In the test group, two eyes necessitated treatment, with one case of lid irritation and one case of contact lens-induced redness, both identified via slit lamp examination.

The findings from this clinical investigation demonstrate comparable clinical performance between the test lens (Interojo 45 Silicone Hydrogel Contact Lens) and the control lens (BAUSCH + LOMB ULTRA (samfilcon A) Contact Lens) when evaluated against both primary and secondary study endpoints. Specifically, biomicroscopy assessments, incidence of adverse reactions, and vision safety metrics—including keratometric changes, refractive changes, and best corrected visual acuity—exhibited no clinically significant differences between the two lens groups. Collectively, these data substantiate the clinical safety and efficacy of both lens types and support the assertion of substantial equivalence.

VIII. CONCLUSIONS

Validity of Scientific Data

Laboratories under Good Laboratory Practice regulations conducted toxicology, microbiology, and stability studies following scientific protocols. The data were determined to be scientifically valid under 21 CFR 860.7.

Substantial Equivalence

Information presented in this Premarket Notification establishes that the **Interojo 45 (inofilcon A) Soft (Hydrophilic) Silicone Hydrogel Contact Lens with GrabSoo Plus** is as safe and effective as the predicate device when used in accordance with the labeled directions for use and for the proposed indication.

Risks and Benefits

The risks of the subject device are the same as those normally attributed to the wearing of soft (hydrophilic) daily wear contact lenses. The benefits to the patient are the same as those for other soft (hydrophilic) daily wear contact lenses.