



October 8, 2024

Lucens Technology Co., Ltd
C/o Bret Andre
Principal Consultant
Andre Vision and Device Research
6119 Canter Lane
West Linn, OR 97068

Re: K242391

Trade/Device Name: Lucens 41 (senofilcon C) Silicone Hydrogel Soft (Hydrophilic) Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: August 8, 2024
Received: August 12, 2024

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 titled "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,

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

Indications for Use

510(k) Number (if known)

K242391

Device Name

Lucens 41 (senofilcon C) Silicone Hydrogel Soft (Hydrophilic) Contact Lens

Indications for Use (Describe)

Sphere:

The Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens in the spherical design is indicated for daily wear for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 1.00 diopter or less that does not interfere with visual acuity.

Toric:

The Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens in the toric design is indicated for daily wear for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -2.25 diopters.

Multifocal:

The Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens in the multifocal design is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and with add powers from +0.25 to +4.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 1.00 diopter or less that does not interfere with visual acuity.

Multifocal-Toric:

The Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens in the multifocal-toric design is indicated for daily wear for the optic correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes in powers of -20.00 to +20.00 diopters with add powers from +0.25 to +4.00 diopters and astigmatism corrections from -0.25 to -2.25 diopters.

Eye Care Practitioners may prescribe the Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement, or for single-use disposable wear.

When prescribed for frequent/planned replacement, the Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens is to be cleaned, rinsed and disinfected each time the lens is removed. The contact lens is to be discarded after the recommended wearing period as prescribed by the Eye Care Professional. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection only.

When prescribed for single-use disposable wear, Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens is to be discarded after each removal.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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: K242391

I. SUBMITTER

Date Prepared: September 9, 2024

Name: **LUCENS TECHNOLOGY Co., Ltd.**

Address: 8F.-1, No. 31, Xintai Rd.,
Zhubei City, Hsinchu County,
Taiwan (R.O.C.).

Contact Person: Kari Huang
Section Manager

Phone number: +886-3-450-1986

Consultant: Bret Andre
EyeReg Consulting, Inc.
6119 Canter Ln.
West Linn, OR 97068

Phone number: (503) 372-5226

II. DEVICE

Trade Name: **Lucens 41 (senofilcon C) Silicone Hydrogel Soft (Hydrophilic) Contact Lens**

Common
Name: Contact Lens, Daily Wear

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

Regulatory
Class: Class II

Product Codes: LPL; MVN

Purpose of 510(k) Submission: ~ New Device ~

III. PREDICATE DEVICE

The **Lucens 41 (senofilcon C) Silicone Hydrogel Soft (Hydrophilic) Contact Lens** is substantially equivalent to the following predicate device:

- **“ACUVUE (senofilcon C) Soft Contact Lens”**
By Johnson & Johnson Vision Care, Inc.
510(k) number; **K160212**
Primary Predicate

IV. DEVICE DESCRIPTION

The **Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens** is for daily wear and is fully molded in the sphere, toric, multifocal and multifocal-toric design configurations. The hydrophilic characteristics allow aqueous solutions to enter the lens. The lenses are fabricated from senofilcon C, which contains silicone hydrogel material and other hydrophilic monomers. The lens consists of 59.0% senofilcon C and 41.0% water by weight when immersed in saline solution. The senofilcon C name has been adopted by the United States Adopted Names Council (USAN).

The **Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens** contains Reactive Blue 246 (21 CFR Part 73.3106) for visibility and handling. The **Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens** incorporates a benzotriazole UV blocking monomer to help protect against transmission of harmful UV radiation. The lens blocks >95% in the UVB range (280nm - 315nm), and >50% in the UVA range (315nm - 380nm). The material properties and available parameters of the finished lenses are as follows:

Parameter	Range	Tolerance
Chord Diameter	13.00 mm to 15.00 mm	±0.20 mm
Center Thickness	0.050 mm to 0.580 mm	When ≤ 0.10 mm → ±0.010 mm + 10% When > 0.10 mm → ±0.015 mm + 5%
Base Curve	8.0 mm to 9.8 mm	±0.20 mm
Back Vertex Power (F'v)	-20.00 D to +20.00 D (in 0.25 D 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)	-0.25 D to -2.25 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)	When 0.00 < F'c ≤ 1.50 D → ± 8° When F'c > 1.50 D → ± 5°
Multifocal Power	+0.25 D to +4.00 D (in 0.25 D steps)	±0.25D
Oxygen Permeability ($\times 10^{-11}$ (cm ² •ml O ₂)/(sec•ml•mmHg))	103	±20%
Visible Light Transmittance	>89%	±5%
Ultraviolet radiation Transmittance	< 5% T _{UVB} <50% T _{UVA}	T _{UVB} (280 to 315nm) < 0.05 T _V T _{UVA} (315 to 380nm) < 0.05 T _V
Water Content	41%	±2%
Refractive Index	1.420	±0.005

V. INDICATIONS FOR USE

Sphere:

The Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens in the spherical design is indicated for daily wear for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 1.00 diopter or less that does not interfere with visual acuity.

Toric:

The Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens in the toric design is indicated for daily wear for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -2.25 diopters.

Multifocal:

The Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens in the multifocal design is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and with add powers from +0.25 to +4.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 1.00 diopter or less that does not interfere with visual acuity.

Multifocal-Toric:

The Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens in the multifocal-toric design is indicated for daily wear for the optic correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes in powers of -20.00 to +20.00 diopters with add powers from +0.25 to +4.00 diopters and astigmatism corrections from -0.25 to -2.25 diopters.

Eye Care Practitioners may prescribe the Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement, or for single-use disposable wear.

When prescribed for frequent/planned replacement, the Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens is to be cleaned, rinsed and disinfected each time the lens is removed. The contact lens is to be discarded after the recommended wearing period as prescribed by the Eye Care Professional. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection only.

When prescribed for single-use disposable wear, Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens is to be discarded after each removal.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The **Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens** is substantially equivalent to the primary predicate device (K160212) in the following areas:

- FDA category - Group V
- FDA classification – Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
- Product codes: LPL; MVN
- USAN Material (senofilcon C)
- Intended use – daily wear contact lenses
- Actions
- Indications for use
- Lens design configurations
- Benzotriazole UV absorbing monomer
- Cast molded production method
- Injection molded polypropylene blister packaging

The following matrix illustrates the production method, lens function and material characteristics of the **Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens**, as well as the predicate device.

	Lucens 41 By LUCENS TECHNOLOGY Co., Ltd. (Subject Device)	ACUVUE Soft Contact Lens By Johnson & Johnson Vision Care, Inc. (K160212)
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)
FDA Classification Product Code(s)	LPL; MVN	LPL; MVN
FDA Group	FDA Group V	FDA Group V
USAN name	senofilcon C	senofilcon C
Water Content (%)	41±2%	41±2%
Oxygen Permeability $\times 10^{-11} (\text{cm}^2/\text{sec})(\text{mlO}_2)/(\text{ml} \times \text{mmHg} @ 35^\circ\text{C})$ (revised Fatt method)	103	103
Refractive Index (hydrated)	1.420	1.420
UV Blocker	Yes - benzotriazole	Yes - benzotriazole
Manufacturing	Cast-Molded	Cast-Molded
Color	Blue Handling Tint Reactive Blue 246	Blue Handling Tint Reactive Blue Dye #4
Packaging	PP Blister Pack	PP Blister Pack

The following matrix compares the indications for use of the **Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens** with the predicate device.

	Indications for Use
Lucens 41 By LUCENS TECHNOLOGY Co., Ltd. (Subject Device)	Sphere: The Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens in the spherical design is indicated for daily wear for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 1.00 diopter or less that does not interfere with visual acuity. Toric: The Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens in the toric design is indicated for daily wear for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -2.25 diopters. Multifocal: The Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens in the multifocal design is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and with add powers from +0.25 to +4.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 1.00 diopter or less that does not interfere with visual acuity. Multifocal-Toric: The Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens in the multifocal-toric design is indicated for daily wear for the optic correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes in powers of -20.00 to +20.00 diopters with add powers from +0.25 to +4.00 diopters and astigmatism corrections from -0.25 to -2.25 diopters. Eye Care Practitioners may prescribe the Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement, or for single-use disposable wear. When prescribed for frequent/planned replacement, the Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens is to be cleaned, rinsed and disinfected each time the lens is removed. The contact lens is to be discarded after the recommended wearing period as prescribed by the Eye Care Professional. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection only. When prescribed for single-use disposable wear, Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens is to be discarded after each removal.
ACUVUE Soft Contact Lens Johnson & Johnson Vision Care, Inc. (K160212)	ACUVUE® (senofilcon C) Soft (hydrophilic) Contact Lens (spherical) is indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism. ACUVUE® (senofilcon C) Soft (hydrophilic) Contact Lens – TORIC is indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 10.00D or less of astigmatism.

	ACUVUE® (senofilcon C) Soft (hydrophilic) Contact Lens – MULTIFOCAL is indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes who may need up to 4.00D of ADD power and may have 0.75D or less of astigmatism. ACUVUE® (senofilcon C) Soft (hydrophilic) Contact Lens – MULTIFOCAL-TORIC is indicated for daily wear for the optical correction of refractive ametropia (myopia, hyperopia and/or astigmatism) and presbyopia in phakic or aphakic persons with non-diseased eyes who may need up to 4.00D of ADD power and may have 10.00D or less of astigmatism. These lenses contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye. Eye Care Professionals may prescribe the lenses either for daily disposable wear or frequent/planned replacement wear with cleaning, disinfection and scheduled replacement (see REPLACEMENT SCHEDULE). When prescribed for daily disposable wear, lenses should be discarded upon removal. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection system only. The contact lens is to be discarded after the recommended wearing period as prescribed by the Eye Care Professional.
--	---

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 performed to demonstrate the safety and effectiveness of the **Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens**. The results support the claim that the **Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens** is substantially equivalent to the currently marketed predicate devices. Refer below to a summary of the results from the non-clinical studies.

Toxicology:

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 packaging solution, and extracts from the finished lenses and packaging materials are not cytotoxic.
- Systemic Toxicity: The finished lenses and 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. The packaging solution and extracts from finished lenses and packaging materials produced no ocular irritation.

Shelf Life:

Testing was performed to evaluate the stability, sterility, and package integrity of the **Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens** over the duration of the labeled expiration date. The data presented supports establishment of the proposed shelf life.

Performance Testing - Bench:

The following bench tests were completed: refractive index, water content, Dk, % transmission (visible & UV), tensile strength, modulus, % elongation to break, specific gravity and quantification of polymerization residuals. Results of physicochemical and mechanical property testing demonstrate consistent material properties between the **Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens** and the predicate device.

Clinical Testing

Contact lenses manufactured from senofilcon C (USAN) material are currently marketed in the United States. Clinical performance testing for the **Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens** is not required for this application.

VIII. CONCLUSIONS

Validity of Scientific Data

Laboratories under Good Laboratory Practice regulations conducted toxicology and microbiology 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 **Lucens 41 (senofilcon C) Silicone Hydrogel Daily Wear Soft (Hydrophilic) Contact Lens** 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.