September 16, 2025

Medicel AG
Erik Braziulis
Regulatory Affairs Manager
Dornierstrasse 11
Altenrhein, 9423
Switzerland

Re: K252540
Trade/Device Name: ACCUJECT Injector Set 2.1-1P (LP604590)
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I, reserved
Product Code: MSS
Dated: August 11, 2025
Received: August 12, 2025

Dear Erik Braziulis:

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.

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,

Jinrong (Jinny) Liu

For Bennett Walker, 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.

510(k) Number *(if known)*
K252540

Device Name
ACCUJECT Injector Set 2.1-1P

Indications for Use *(Describe)*
The ACCUJECT IOL Injector is indicated to fold and insert BVI IOLs approved for use with this injector in the human eye.

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.

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"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."

September 11th, 2025

Medicel AG
% Erik Braziulis
Regulatory Affairs Manager
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Switzerland

510(k) Summary

510(k) number	**K252540**
Date:	September 11th, 2025
Submitter:	Medicel AG Dornierstrasse 11 9423 Altenrhein Switzerland
Contact Person:	Erik Braziulis Regulatory Affairs Manager Phone: +41-71-727-0947 Email: e.braziulis@medicel.com
Trade name: REF Regulation:	ACCUJECT 2.1-1P Injector Set LP604590 21 CFR 886.4300 - Intraocular lens guide
Product Code:	MSS
Predicate Device:	B&L IOL injector System, INJ100 (K113852)
Device Description:	The ACCUJECT Injector Set is an assembled injection system that is single use with a silicone cushion tip that is used to push forward and insert the IOL that has been placed in a single use cartridge into the eye. As the lens enters the tip it is folded and compressed.
Indications for Use:	The ACCUJECT IOL Injector is indicated to fold and insert BVI IOLs approved for use with this injector in the human eye.
Comparative Analysis:	The Medicel lens injector ACCUJECT Injector Set 2.1-1P is substantially equivalent to the predicate device.
Functional Testing:	The ACCUJECT IOL Injector has successfully completed functional testing and has been found to deliver BVI IOLs in conformance with the requirements in ISO 11979-3.
Conclusion:	The ACCUJECT IOL Injector is substantially equivalent to the predicate device.

Comparison of Predicate to the Medicel injector ACCUJECT 2.1-1P Injector Set

Characteristics	Predicate K113852 B&L IOL injector System, INJ100	Proposed Device Medicel IOL Injector, ACCUJECT 2.1-1P Injector Set
Indications for Use	The Bausch + Lomb IOL Injector is indicated for folding and injection of Bausch + Lomb IOLs approved for use with this injector.	The ACCUJECT IOL Injector is indicated to fold and insert BVI IOLs approved for use with this injector in the human eye.
Contraindications	None	None
Anatomical site	Eye	Eye
Fundamental Technology	An assembled injection system that is single use with a silicone cushion tip that is used to push forward and insert the IOL that has been placed in a single use cartridge into the eye. As the lens enters the tip it is folded and compressed.	An assembled injection system that is single use with a silicone cushion tip that is used to push forward and insert the IOL that has been placed in a single use cartridge into the eye. As the lens enters the tip it is folded and compressed.
Materials	Cartridge tip: PEBAX 7033 SA 01 MED + Medicoat A Loading chamber: Polypropylene Injector body: ABS Plunger: ABS Silicone Cushion: Silicone Spring: Stainless Steel Packaging (Lid): Tyvek 1073B Packaging (Blister): Eastar Copolyester 6763	Cartridge tip: PEBAX 7033 SA 01 MED + Medicoat A Loading chamber: Polypropylene Injector body: MABS Plunger: ABS Silicone Cushion: Silicone Spring: Stainless Steel Packaging (Lid): Tyvek 1073B Packaging (Blister): Eastar Copolyester 6763
Coating of cartridge tip	Medicoat A coating	Identical coating process
Dimensions	Cartridge 2.1 Ø: - oval-shape - Incision Size: 2.4mm	Cartridge 2.1 Ø: - oval-shape - Incision Size: 2.4mm

	Plunger without stopper -	Plunger with stopper for reducing the plunger travel
	Injector Body: - Bausch + Lomb logo - Finger flanges at the end	Injector Body: - Medicel logo - Finger flanges advanced
	All other dimensions	same
Single use	Yes	Yes
Is this product sterile	Yes	Yes
Method of Sterilization	Ethylene oxide (EO)	Ethylene oxide (EO)
Shelf Life	24 months	36 months
Manufactured by	Medicel AG	Medicel AG
How supplied	Sterile blister of one injector	Sterile blister of one injector

Conclusion: The Medicel lens injector ACCUJECT 2.1-1P Injector Set is substantially equivalent to the predicate device. As summarized above, the ACCUJECT IOL injector and the predicate device share the same intended use, indications, operating principle, packaging and sterilization method. The minor dimensional differences in the Injector body, plunger, cartridge tip and injector body material between the devices are considered clinically not significant.

Brief Summary of Nonclinical Test and Results:

The following design verification activities were identified:

1. Biocompatibility testing (leveraged from predicate device)
2. Functional / Shelf-life testing (proposed device tested with BVI FINEVISION HP IOL's)
3. EO residual testing (proposed device tested with BVI FINEVISION HP IOL's)
4. Particulate testing (conducted on INJ100 with IOLs representative of BVI FINEVISION HP IOLs)

Results from validation testing of the ACCUJECT 2.1-1P Injector Set demonstrate that the injector functions as intended. In accordance with applicable tests in ISO 11979-3:2012 Ophthalmic implants -- Intraocular lenses -- Part 3: Mechanical properties and test methods (i.e., Section 5, Recovery of Properties following simulated surgical manipulation), intraocular lenses recovered to specifications after being folded and deformed by the Injector.

The ACCUJECT 2.1-1P Injector Set has been evaluated and tested for biocompatibility to ensure that the injector meets the requirements of ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

Non-Clinical Study Results:

Study	**Result**	**Is the Subject Device as safe and effective as the Predicate Device?**
Biocompatibility	The biocompatibility tests performed met all acceptance criteria.	Yes
Functional / Shelf-life	All functional and shelf-life testing performed met all acceptance criteria.	Yes
EO Residual testing	The EO residual testing met all acceptance criteria	Yes
Particulate	The particulate testing met all acceptance criteria	Yes

The data generated from the non-clinical studies of the subject device, ACCUJECT 2.1-1P Injector Set, support the subject device substantial equivalence to the predicate device.

The comparison of technical characteristics and data generated from the non-clinical studies demonstrate the substantial equivalence of the subject device and the predicate device.