September 19, 2023

Medicel AG
% Dan Lew
Manager of Regulatory Affairs
STAAR Surgical
1911 Walker Avenue
Monrovia, California 91016

Re: K231106
Trade/Device Name: ACCUJECT™ REFRA Injector, Model AR2900
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I, reserved
Product Code: MSS
Dated: August 9, 2023
Received: August 10, 2023

Dear Mr. Lew:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Bennett N. Walker -S

Digitally signed by Bennett N. Walker -S
Date: 2023.09.19 12:47:56 -04'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231106

Device Name
ACCUJECT™ REFRA Injector (AR2900)

Indications for Use *(Describe)*
The ACCUJECT™ REFRA Injector is a device intended to fold and insert STAAR Surgical Collamer Phakic One Piece Intraocular Lenses, Model EVO/EVO+ VISIAN® Implantable Collamer® Lens, for surgical placement 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.

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510(k) Summary

Date:	September 19, 2023
Submitter:	Medicel AG Dornierstrasse 11 9423 Altenrhein Switzerland
Contact Person:	STAAR Surgical Company Dan Lew Manager of Regulatory Affairs Phone: 626-303-7902 Email: dlew@staar.com
Trade name:	Medicel ACCUJECT™ REFRA Injector
Regulation:	21 CFR 886.4300 - Intraocular lens guide
Product Code:	MSS
Predicate Device:	Visian nanoPOINT™ 2.0 Injector (K101134)
Device Description:	The Medicel ACCUJECT™ REFRA Injector System, Model AR2900 is to be used by an ophthalmic surgeon and is intended to facilitate the loading, folding and insertion of the STAAR Surgical Collamer Phakic One Piece Intraocular Lenses, Model EVO/EVO+ VISIAN® Implantable Collamer® Lens, for surgical placement in the human eye. The ACCUJECT™ REFRA is a single use device designed specifically to deliver the STAAR Surgical Implantable Collamer® Lenses.
Indications for Use:	The ACCUJECT™ REFRA Injector is a device intended to fold and insert STAAR Surgical Collamer Phakic One Piece Intraocular Lenses, Model EVO/EVO+ VISIAN® Implantable Collamer® Lens, for surgical placement in the human eye.
Comparative Analysis:	The ACCUJECT™ REFRA Injector has been demonstrated to be equivalent to the predicate device for their intended use.
Functional Testing:	The ACCUJECT™ REFRA Injector have successfully completed functional testing and have been found to deliver Visian ICLs in conformance with the requirements in ISO 11979-3.
Conclusion:	The ACCUJECT™ REFRA Injector is substantially equivalent to the predicate device.

Characteristic	Predicate Device (K101134)	Subject Device (K231106)
	Visian nanoPOINT™ 2.0 Injector Model LP604430	Proposed ACCUJECT™ REFRA Injector, Model AR2900
Product Description	This Injector and Cartridge System is a sterile, single-use device intended to fold and insert a STAAR Surgical Collamer phakic one piece intraocular lens through surgical procedure in a human eye. The system provides a tubular pathway through an incision over the iris, allowing delivery of a phakic IOL into the human eye.	Same
Intended use	The Visian® nanoPOINT™ 2.0 Injector System is a device intended to fold and insert STAAR Surgical Collamer® Phakic one-piece Intraocular Lenses, Model Visian® ICL, for surgical placement in the human eye.	Same (as modified to include update of new branding) The ACCUJECT™ REFRA Injector is a device intended to fold and insert STAAR Surgical Collamer Phakic One Piece Intraocular Lenses, Model EVO/EVO+ Visian® Implantable Collamer® Lens, for surgical placement in the human eye.
Operating Principle	A phakic IOL is loaded into a cartridge, then pushed through the cartridge by pushing the plunger to deliver into a human eye.	A phakic IOL is loaded into a cartridge, then pushed through the cartridge by pushing or twisting the plunger to deliver into a human eye.
Materials	Cartridge tip: Polypropylene Cartridge loading chamber: Polypropylene	Cartridge tip: Polyamide coated with Medicoat A Cartridge loading chamber: Polypropylene coated with Medicoat A
	Injector body and finger flanges & Plunger body: ABS	Same
	Plunger tip: Silicone	Same
	Spring: stainless steel	No spring used
	No buffer	Silicone buffer
Sterile	Yes, EtO.	Same
Packaging	Blister sealed with a Tyvek lid. 10-pack box.	Same
Shelf life	3 years	1 year
Manufacturer	Medicel AG	Same

The technological characteristics of the modified ACCUJECT™ REFRA Injector are substantially equivalent to the predicate nanoPOINT™ Injector, cleared in K101134. As demonstrated above, the ACCUJECT™ REFRA Injector and nanoPOINT™ Injector share the same intended use, indications, operating principle, design, packaging and sterilization method.

Brief Summary of Nonclinical Test and Results:

Results from validation testing of the ACCUJECT™ REFRA Injector 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™ REFRA Injector has been 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?**
Recovery of Properties	The change in injector design does not impact the performance characteristics of the injector cartridge or lens.	Yes
Biocompatibility	The biocompatibility tests performed on the modified injector met all acceptance criteria.	Yes
Particulate	The particulate testing performed on the modified injector met all acceptance criteria.	Yes

The data generated from the non-clinical studies of the subject device, ACCUJECT™ REFRA Injector, 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.