October 8, 2021

New World Medical, Inc.
Victor Arellano
Global Regulatory Affairs Manager
10763 Edison Court
Rancho Cucamonga, California 91730

Re: K211680
Trade/Device Name: Streamline® Surgical System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: MRH, HMX
Dated: August 27, 2021
Received: September 1, 2021

Dear Victor Arellano:

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,

for LCDR Charles Chiang
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)*
K211680

Device Name
Streamline® Viscoelastic Injector

Indications for Use *(Describe)*

The Streamline® Viscoelastic Injector is a single-use disposable cannula for use during ophthalmic surgical procedures to deliver small amounts of viscoelastic fluid.

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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This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92(c).

Submitter Information

510(K) Owner Name: New World Medical, Inc
10763 Edison Court
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USA (909) 466-4304

Contact Information: Victor Arellano
Global Regulatory Affairs Manager
New World Medical, Inc.
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Email: varellano@newworldmedical.com

Date Prepared: October 7, 2021

Device Name and Classification

Trade / Proprietary Name:	Streamline® Viscoelastic Injector	
Device Common Name:	Viscoelastic Injector	
Classification Names:	Pump, Infusion	Cannula, Ophthalmic
Regulation Numbers	21 CFR 880.5725	21 CFR 886.4350
Device Classification:	Class II	Class I
Product Codes	MRH (Infusion Pump, Ophthalmic)	HMX (Ophthalmic Cannula)

Predicate Device:

Device Name	**510(k) Number**
OMNI™ Surgical System	K173332

Intended Use

The Streamline® Viscoelastic Injector is intended to deliver small amounts of viscoelastic fluid during Ophthalmic Surgery.

Indications for Use

The Streamline® Surgical System is a single-use disposable cannula for use during ophthalmic surgical procedures to deliver small amounts of viscoelastic fluid.

Device Description and Technological Characteristics

The Streamline® Viscoelastic Injector is a single use disposable device designed to deliver small amounts of viscoelastic fluid.

The device consists of a single-use disposable device comprised of a surgical grade stainless steel cannula and a polymer handset, actuator button and priming port (Figure 1). The cannula is comprised of a long thin neck with an outer sleeve at its tip and allows access through a minimum 1.8 mm clear corneal incision. The cannula is long enough to reach across the eye 180 degrees from the clear corneal incision.

The device outer sleeve is transparent which allows the dispensing cannula with a clearly identifiable color to be visible at 12X magnification.

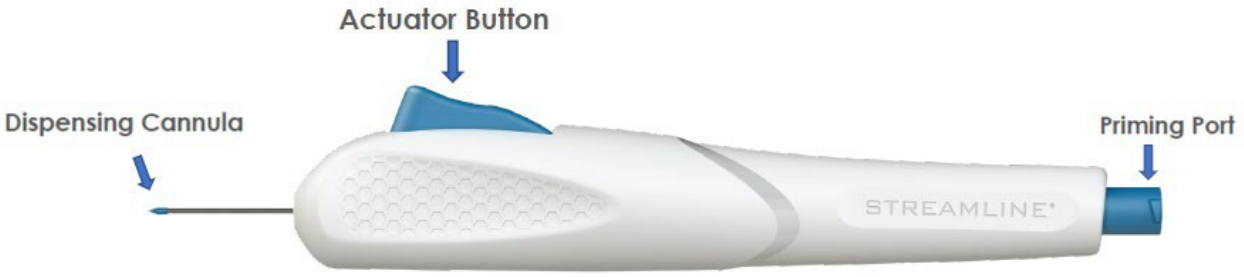

Figure 1

The priming port allows interfacing with commonly used viscoelastic containers used during priming and filling of the device.

The actuator button is located at the top of the handset and is colored for easy identification and incorporates a slight depression giving the user a tactile feel and correct finger placement. Each actuation of the actuator button causes an internal mechanical cam to rotate causing a snap action which rapidly retracts the outer sleeve at the device's distal tip. This action allows the cannula to dispense viscoelastic fluid through opposing side outlets located at an acute angle from the perpendicular plane of tip (Figure 2).

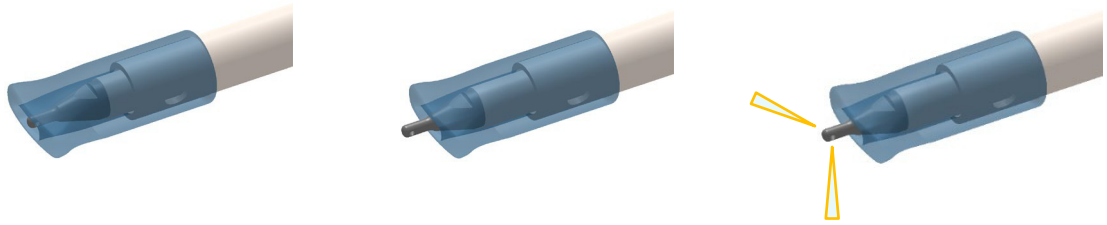

Figure 2

The length of the gear assembly allows for up to eight (8) total activations of the device. Each activation of the delivers approximately 7 µL of OVD and approximately 56 µL of OVD for the total maximum 8 activations allowed by the device. Once all activations are completed the gear assembly will have reached the end of travel and cannot be reset. Additionally, activation of the actuator button causes the priming port to disengage from the fluid pathway, to prevent re-priming of the device. This prevents the device from further priming preventing re-use.

Materials used to manufacture the Streamline® Viscoelastic Injector are of medical grade quality and no toxic substances are used in the manufacturing process. The materials used in the Streamline® Viscoelastic Injector were selected from materials safe for use in a clinical setting. These materials include stainless steel, polycarbonate, ABS polymer and silicone.

Comparison of Technological Characteristics with the Predicate Device

The technical features of the Streamline® Viscoelastic Injector are substantially equivalent to the predicate device Sight Sciences Omni Surgical System (K173332).

The Streamline® Viscoelastic Injector and predicate device Sight Sciences Omni Surgical is a manually operated device for the controlled delivery of small amounts of viscoelastic fluid and dispenses these fluids based on the principle of exchanging volumes much like a syringe.

The following Table 2 compares the attributes of the Streamline® Viscoelastic Injector with the predicate device.

Table 2 – Streamline® Attribute Comparison

Characteristic	NWM Streamline® Viscoelastic Injector(Subject Device)	OMNI™ SurgicalSystem (Primary Predicate)K173332
Class	II	II
Product Code	Primary: MRH (Ophthalmic Infusion Pump, Class II) Secondary: HMX (Class I, Exempt) for Ophthalmic Cannulas	Primary: MRH (Ophthalmic Infusion Pump) Secondary: HMZ(Trabeculotome)
Regulation	Primary: 880.5725(Infusion Pump) Secondary: 886.4350(Manual Ophthalmicsurgical instrument)	Primary: 880.5725(Infusion Pump) Secondary: 886.4350(Manual ophthalmic surgical instrument)
Intended Use	Delivery of small amounts of viscoelastic fluid during Ophthalmic Surgery	Delivery of small amounts of viscoelastic fluid during Ophthalmic Surgery Creation of incisions within the trabecular meshwork.
Indications forUse	The Streamline® Viscoelastic Injector isa single-use disposablecannula for use during ophthalmic surgical procedures to deliver small amounts of viscoelastic fluid.	The OMNI™ Surgical System is a manually operated device for delivery of small amounts of viscoelastic fluid, for example Healon® or Healon GV® from Abbott Medical Optics (AMO),Amvisc® from Bausch & Lomb, or PROVISC® from Alcon, during ophthalmic surgery. It is also indicated to cut trabecular meshwork tissue during trabeculotomyprocedures.
Technical Characteristics	• Cannula • Internal reservoir • Plunger tube • Actuator Button	• Cannula • Microcatheter • Internal reservoir • Plunger tube • Finger wheel

Characteristic	NWM Streamline® Viscoelastic Injector(Subject Device)	OMNI™ SurgicalSystem (Primary Predicate)K173332
Target Anatomy	Anterior Chamber	Schlemm's Canal/TrabecularMeshwork
Operating Principle	Manual	Manual
Design / Mechanism ofAction	• Lumen has a round, bolus, atraumatic tip fordispensing of viscoelastic. • Retractable medical grade transparent colored outer sleeve to enhance visibility undermagnification. • Proximal handledesigned for ambidextrous use. • Handle has internalviscoelastic reservoir and plunger tube • Finger actuated buttonfor retracting sleeve anddispensing viscoelastic fluid. • Device cannula is long enough to reach across the eye180 degrees from the corneal incision. • Device dispensing cannula has opposing outlets at an acute angleto dispense viscoelasticfluid. • Device actuation button provides audible click when activating.	• Stainless-steel cannulahas sharp tip that can beused to pierce the trabecular meshwork and provide access into Schlemm's canal. Minordimensional changes to cannula tip height and radius • Flexible microcatheterwith rounded, atraumatic tip for dispensing of viscoelastic • Microcatheter is bluecolor to facilitate its visibility in Schlemm'scanal as it is advanced/retracted through the cannula • Microcatheter allowsaccess to 360° of Schlemm's canal in two 180° segments • Proximal handle changed to ovoid shape with elastomeric material for added grip • Proximal handle allows ambidextrous use ineither patient eye • Internal viscoelastic reservoir and plunger tube with dimensionalchanges to allow dispensing ofviscoelastic

Characteristic	NWM Streamline® Viscoelastic Injector(Subject Device)	OMNI™ SurgicalSystem (Primary Predicate)K173332
		• Ovoid handle shape allows advancement wheels (finger wheels) to be reduced to two foradvancing and retracting microcatheter up to 20mm using a rack and pinion mechanism • Tactile and audible clicks indicate precise advancement • Viscoelastic dispensedduring retraction of firsttwo cycles after priming with viscoelastic fluid • Flexible microcatheterintroduced into Schlemm's canal and pulled through to cut trabecular meshwork • Priming Lock moved to accommodate new Luerfitting and prevents accidental dispensing during viscoelastic priming • Changes were made tothe materials in the handle, reservoir, Luer fitting and new bonding adhesive wasused
Viscoelastic	Supplied separatelyfrom unaffiliated manufacturers. Viscoelastic loaded intodevice prior to use by attaching OVD cartridge directly to a Luer fitting located at the proximal end of the device handle for easeof priming.	Cohesive viscoelasticfluid (OVD or ophthalmic viscosurgical device) issupplied separately. Viscoelastic loaded into device (primed) prior to use by attachingOVD cartridge directly to a Luer fitting that replaces the cap on proximal end of OMNIdevice handle for ease of priming

Characteristic	NWM Streamline® Viscoelastic Injector (Subject Device)	OMNI™ SurgicalSystem (Primary Predicate)K173332
Sterile andSingle Use	Provided sterile. Singleuse.	Provided sterile. Singleuse.
Passive or Energized Device to Dispense Viscoelastic	Passive	Passive
DispensingControl	Manual depression ofActuator Button to dispense viscoelastic fluid	After priming, viscoelastic dispensing control occurs through manual rotationof either advancement wheel at the distal end of the device. Synchronization of the two wheels was reversed for ease of use
Dispensing Mechanism	Syringe (Volumeexchange)	Syringe (Volumeexchange)
OVD Volume Dispensed	7 µL	11 µL
Materials	Medical grade materialsincluding: • Cannula – StainlessSteel • Polycarbonate tipsleeve • ABS molded primingport Silicone seals	Medical grade materials,including ABS, polycarbonate, stainless steel, silicone, parylene coating, cyanoacrylate, acrylate edurethane, polyimide
Interface	Handheld	Handheld
Catheter / Cannula Shaft / Probe OD	150 microns	483 microns
MicrocatheterTip Outer Diameter	≤ 0.007 inches (< 178 microns)	0.0090 to 0.0110 inches (229 to 279 microns)

Performance Testing

Extensive non-clinical testing of the Streamline® Viscoelastic Injector has been performed to fulfill the traceability of design input and output matrix addressing all relevant test criteria for the device type. The requirements are driven by established standards and include the following:

Functional Performance Testing, Design Verification

Testing was based on all applicable standards, as well as, testing to demonstrate conformance to design specifications. Test samples exposed to maximum gamma sterilization, distribution simulation, environmental conditioning, and accelerated aging for 1-year shelf life.

- Joint Strength Testing
  - Quantitative tensile strength testing of all patient interfacing cannula and over-molded polymer joints using Instron with validated test methods, assuring cannula integrity for anticipated forces during use.
  - Bend testing of patient interfacing cannula under maximum expected loading during use, using Instron with validated test method.
  - Strength of priming port interface qualitatively confirmed for all test units through simulated use and visual inspection under protocol.
- Drivetrain motion functional testing
  - Qualitatively verify activation of the Actuator Button causes the desired drivetrain motion via visual inspection during multiple button actuations, with one side housing removed (100% of units during sample build).
  - Verify Maximum Recommended Cycles - Qualitatively verify activation of Actuator Button results in fluid being dispensed and mechanism resets for maximum number of cycles recommended in IFU.
- Actuator Button force.
  - Quantitative test measuring force required to fully depress Actuator Button using Instron, validated test method, and a range of viscoelastic fluids.
  - Visually verify units dispense fluid and the mechanism resets for maximum number of cycles recommended in the IFU.
- Dispense volume testing
  - Quantitatively test under validated test methods measuring amount of dispensed viscoelastic fluid per Actuator Button activation for different viscoelastic fluids over maximum number of cycles recommended in the IFU.
- Leak Testing
  - Quantitatively test fluid pathway seals and duckbill valve via 100% pressure decay tests during sample build.
- Cadaver evaluation
  - Qualitatively verify delivery using viscoelastic fluid dyed with Trypan Blueon cadaver eyes.
- Human Factors Engineering Evaluation
  - Human Factors Engineering evaluation utilizing 15 surgeons in simulated surgical suite, working through all stages of unpacking, presenting to sterile field, priming and using device per label/ instructions for use.

- Biocompatibility
  - Biocompatibility assessment within a risk management framework per ISO 10993-1 Fifth Edition 2018-08. The following tests will be completed:
  - Cytotoxicity as per the requirements established in ISO 10993-5, Biological Evaluation of Medical Devices -- Part 5, Annex C : MTT Cytotoxicity test.
  - Sensitization as per the requirements established in 10993-10, Biological Evaluation of Medical Devices -- Part 10: Tests For Irritation And Skin Sensitization.
  - Irritation or Intracutaneous Reactivity in accordance with FDA GLP Regulations, 21 CFR 58
  - Acute Systemic Toxicity as per the requirements established in 10993-11, Biological Evaluation of Medical Devices -- Part 11: Tests for Systemic Toxicity.
  - Material-Mediated Pyrogenicity as per the requirements established in 10993-11, Biological Evaluation of Medical Devices -- Part 11: Tests For Systemic Toxicity, and USP 43-NF 38 General Chapter <151 >, Pyrogen Test.
- Chemical characterization testing of materials per EN ISO 10993-18:2009.
- Package Integrity for 1-year shelf life
  - Demonstration of package integrity per EN ISO 11607-1 and 2:2019, Requirements for materials, sterile barrier systems and packaging systems. after maximum gamma sterilization, distribution simulation and environmental conditioning. Samples aged in compliance to ASTM F1980-16
    - Visible inspection of seals per ASTM F1886-16
    - Seal strength per ASTM F88-15
    - Seal integrity per ASTM F2096-11
- Luer Fitting Compliance
  - Priming port, female luer connection, confirmed compliance to ISO 80369-7:2016
- Stainless Steel Cannula compliance to ISO 9626:2016

Substantial Equivalence

The Streamline® Viscoelastic Injector meets all product design requirements and applicable standards. The Streamline® Viscoelastic Injector has the same key technological characteristics, and principle of operation as the predicate device. Therefore, the device has been shown to be substantially equivalent to the predicate device.