February 14, 2025

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

Re: K243503
Trade/Device Name: VIA360™ Surgical System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: MRH, HMZ
Dated: January 6, 2025
Received: January 7, 2025

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 (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,

CLAUDINE H. KRAWCZYK -S

Claudine Krawczyk
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)*
K243503

Device Name
VIA360™ Surgical System

Indications for Use *(Describe)*
The VIA360™ Surgical System is indicated for delivery of controlled amounts of viscoelastic fluid during ophthalmic surgery. It is also indicated to cut trabecular meshwork tissue during trabeculotomy procedures.

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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1. 510K Summary

510(K) Owner:	New World Medical, Inc. 10763 Edison Court Rancho Cucamonga, CA 91730
Contact Person:	Victor Arellano Sr. Manager, Global Regulatory Affairs Contact Information: 909-466-4304 ext. 118
Date Prepared:	12 JUL 2024
Device Trade Name:	VIA360™ Surgical System
Classification Number:	21 CFR 880.5725 – Infusion Pump
Product Code:	MRH, HMZ
Regulation Number:	21 CFR 880.5725, 21 CFR 886.4350
Predicate Device	K173332 (OMNI Surgical System)

1.1. Device Description

The VIA360™ Surgical System is a manually operated surgical instrument used by ophthalmologists to deliver controlled amounts of ophthalmic viscoelastic fluid into the anterior segment of the eye. The VIA360™ Surgical System is comprised of a surgical-grade stainless steel cannula and a nylon microcatheter. The cannula is attached to a nose piece that can be rotated to a desired position for use in either eye. The microcatheter is advanced and retracted up to 40 mm per cycle by rotating the scroll wheel. The microcatheter has patterned markings every 10 mm to help measure the extended length. A controlled amount of viscoelastic fluid is dispensed through multiple outlets located on the microcatheter's distal tip by depressing the scroll wheel or the surrounding button. An external reservoir is included for the purpose of priming the device. The device is single-use only.

1.2. Indications for Use

The VIA360™ Surgical System is indicated for delivery of controlled amounts of viscoelastic fluid during ophthalmic surgery. It is also indicated to cut trabecular meshwork tissue during trabeculotomy procedures.

1.3. Summary of Non-Clinical Data

Non-clinical performance verification testing was performed to demonstrate that the subject, The VIA360™ Surgical System is substantially equivalent to the predicate device. Performance testing included joint strength testing, actuation force testing, priming and dispense volume testing, and simulated use testing.

Package integrity testing includes:

Test Performed	Standard/Guidance	Results
Visual Inspection	ASTM F1886 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection	All samples met the acceptance criteria
Seal Strength	ASTM F88 Standard Test Method for Seal Strength of Flexible Barrier Materials	All units had a seal strength > 0.75 lbf/in
Bubble leak test	ASTM F2096 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)	All samples met the acceptance criteria

Biocompatibility testing included:

Test Performed	Standard/Guidance	Results
Cytotoxicity	ISO 10993-5 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Non-Cytotoxic
Sensitization	ISO 10993-10 - Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Non-Sensitizer
Irritation	ISO 10993-10 - Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Non-irritant
Acute Systemic Toxicity	ISO 10993-11 - Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	Non-toxic
Material-Mediated Pyrogenicity	ISO 10993-11 - Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	Non-pyrogenic
Sterilization	ISO 11137-1 - Sterilization of health care products - Radiation - Part 1 ISO 11137-2 -- Sterilization of health care products. Radiation – Part 2: Establishing the sterilization dose	Assurance level of 10^{-6}

Acceptance criteria were based on the ability of the device to perform as intended under its usage conditions and based on predicate device characteristics. The test results show that the VIA360™ Surgical System met all acceptance criteria and performs as intended.

1.4. Summary of Clinical Data:

Clinical data is not included in this submission and is not required. Substantial equivalence is based on technological comparison.

1.5. Comparison of Technological Characteristics with the Predicate Device:

As was established in this submission, the subject device - The VIA360™ Surgical System is substantially equivalent to the predicate K173332 (OMNI™ Surgical System) previously cleared by FDA. The subject device has been shown to be substantially equivalent and has equivalent technological characteristics to its predicate device through comparison in areas including design, labeling/intended use, principles of operation, materials, and function. Additional information can be seen in table 1.6 below.

1.6. Predicate Device Comparison Chart

Characteristics	Subject Device	Predicate Device
Class	II	II
Product Code	**Primary:** MRH (Ophthalmic Infusion Pump, Class II) **Secondary:** HMZ (Trabeculotomy, Manual ophthalmic surgical instrument, Class I exempt)	**Primary**: MRH (Ophthalmic Infusion Pump, Class II) **Secondary**: HMZ (Trabeculotomy, Manual ophthalmic surgical instrument, Class I exempt)
Regulation	**Primary:** 880.5725 (Infusion Pump) **Secondary:** 886.4350 (Manual ophthalmic surgical instrument)	**Primary:** 880.5725 (Infusion Pump) **Secondary:** 886.4350 (Manual ophthalmic surgical instrument)
Intended Use	Delivery of controlled amounts of viscoelastic fluid during ophthalmic surgery	Delivery of small amounts of viscoelastic fluid during ophthalmic surgery
	Cutting of trabecular meshwork when a trabeculotomy is indicated	Cutting of trabecular meshwork when a trabeculotomy is indicated
Indications For Use	The VIA360™ Surgical System is indicated for delivery of controlled amounts of viscoelastic fluid during ophthalmic surgery. It is also indicated to cut trabecular meshwork tissue during trabeculotomy procedures.	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 trabeculotomy procedures.
Target Anatomy	Anterior Segment including Schlemm's Canal/Trabecular Meshwork	Anterior Segment including Schlemm's Canal/Trabecular Meshwork
Operating Principle	Manual	Manual
Dispensing Mechanism	Depression of the scroll wheel/surrounding button to actuate the pump	Manual rotation of the finger wheel (dispensed upon catheter retraction)

Characteristics	Subject Device	Predicate Device
Design	Flexible microcatheter for dispensation of viscoelastic	Flexible microcatheter for dispensation of viscoelastic
	Microcatheter has a round, bolus, atraumatic tip	Microcatheter has a round, bolus, atraumatic tip
	Proximal handle	Proximal handle
	Flexible microcatheter introduced into Schlemm's canal and pulled through to cut trabecular meshwork	Flexible microcatheter introduced into Schlemm's canal and pulled through to cut trabecular meshwork
	Finger wheel for advancing and retracting microcatheter	Finger wheel for advancing and retracting microcatheter
	Viscoelastic fluid is dispensed using scroll wheel/surrounding button.	Viscoelastic dispensed during retraction
	The device contains a separate external reservoir	Handle has internal viscoelastic reservoir and plunger tube
Viscoelastic	Supplied separately. Viscoelastic loaded into the device prior to use.	Supplied separately. Viscoelastic loaded into the device prior to use.
Sterile and Single Use	Provided Sterile. Single Use	Provided Sterile. Single Use
Material	Cannula – Stainless Steel Microcatheter – Polyamide (Nylon)	Cannula – Stainless Steel Microcatheter – Polyamide (Nylon)
Passive or Energized Device to Dispense Viscoelastic	Passive	Passive
Dispensing control	Pressing of the scroll wheel/surrounding button to actuate the pump	Manual rotation of the finger wheel at the distal end of the device
Dispensing Mechanism	Positive displacement pump	Syringe (Volume exchange)
Interface	Handheld	Handheld

Characteristics	Subject Device	Predicate Device
Microcatheter shaft/Probe OD	200 Microns	200 Microns
Cannula	Curved distal end with sharp edge to create incisions	Curved distal end with sharp edge to create incisions

1.7. Conclusion

Based on the indications for use, technological characteristics, non-clinical performance data, and a comparison to the predicate device, the subject device - The VIA360™ Surgical System has been shown to be substantially equivalent to the legally marketed predicate device for its intended use.