May 17, 2024

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

Re: K220891
Trade/Device Name: Kahook Dual Blade Glide (KDB Glide)
Regulation Number: 21 CFR 878.4400
Regulation Name: Knife, Intraocular Pressure Lowering
Regulatory Class: Class II
Product Code: QUQ
Dated: October 23, 2023
Received: October 24, 2023

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.

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
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Respiratory, ENT and Dental Devices
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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)*
K220891

Device Name
Kahook Dual Blade Glide

Indications for Use *(Describe)*
The Kahook Dual Blade Glide is indicated to surgically remove a strip of trabecular meshwork to reduce intraocular pressure in adult patients with primary open angle glaucoma.

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
K220891

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

I. SUBMITTER INFORMATION

510(k) Owner: New World Medical, Inc
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Date Summary Prepared: May 16, 2024

II. DEVICE INFORMATION

Trade / Proprietary Name:	Kahook Dual Blade Glide
Common Name:	Surgical Knife
Regulation Numbers	21 CFR 878.4400
Device Classification:	Class II
Predicate Device:	NMX-1000™, NeoMedix Corporation (K040584)
Reference Device:	OMNI Surgical System, Sight Sciences, Inc. (K202678)

III. DEVICE DESCRIPTION

The Kahook Dual Blade (KDB) Glide is a single-use, ophthalmic knife for use in adults. It is intended to remove a strip of trabecular meshwork tissue to allow for fluid outflow in glaucoma patients. The device is designed for ease of use and easy access to the structures within the eye. The blades are made of surgical-grade stainless steel. The tip of the knife is pointed and allows for easy piercing of tissue. The ramp that the tip is attached to lifts tissue and exposes it to two parallel dual blades of the instrument, effectively remove a narrow strip of tissue.

Figure 1. Kahook Dual Blade Glide (Part# 10-0065)

IV. INDICATIONS FOR USE

The Kahook Dual Blade Glide is indicated to surgically remove a strip of trabecular meshwork to reduce intraocular pressure in adult patients with primary open angle glaucoma.

V. TECHNICAL CHARACTERISTICS (IN COMPARISON TO PREDICATE DEVICE)

New World Medical believes that the Kahook Dual Blade Glide described in this notification and for use under the conditions of the proposed labeling is substantially equivalent to a legally marketed Class II predicate device, the NMX-1000. **Table 1** provides a tabular presentation of the Kahook Dual Blade Glide compared to the predicate device, cleared by FDA in K040584 and intended for use as an ophthalmic surgical tool to surgically remove a strip of trabecular meshwork.

Table 1
Kahook Dual Blade (KDB) Glide Substantial Equivalence

Device Characteristic	Subject Device Kahook Dual Blade Glide	Primary Predicate Device NMX-1000
Regulation	CFR 878.4400	CFR 878.4400
510(k) Number	K220891	K040584
Product Code	QUQ CFR 878.4400	Primary : GEI (Electrosurgical cutting and coagulation device) Secondary : HQR (Apparatus, Cautery, RF, AC-Powered)
Device Class	Class II	Class II
Intended Use	Ophthalmic surgical tool to cut trabecular meshwork	Ophthalmic surgical tool to cut trabecular meshwork
Indications for Use	The Kahook Dual Blade Glide is indicated to surgically remove a strip of trabecular meshwork to reduce intraocular pressure in adult patients with primary open-angle glaucoma.	The NMX-1000 is designed to surgically remove a strip of the Trabecular meshwork for surgical management of infantile and adult glaucoma.
Prescription Status	Prescription use only	Prescription use only
Target Anatomy	Trabecular Meshwork	Trabecular Meshwork
Operating Principle	Manual cutting to remove trabecular meshwork	Bipolar electro-surgical pulse to remove trabecular meshwork
Device Shape	Ramped tip to facilitate lift and stretch of the trabecular meshwork while dual blades create parallel	90 degree tip bent to create triangular footplate to penetrate trabecular meshwork. Feeds trabecular

Device Characteristic	Subject Device Kahook Dual Blade Glide	Primary Predicate Device NMX-1000
	incisions of the trabecular meshwork	meshwork into the ablative bipolar electrodes as the instrument is advanced along Schlemm's canal.
Design/Mechanism of Action	Inserted through a previously created clear corneal incision. The anterior chamber is inflated with viscoelastic. Under gonioscopic evaluation, insert the tip and the neck through the clear corneal incision and advance to the opposite side of the anterior chamber. Engage the trabecular meshwork across from the clear corneal incision with the pointed tip and pierce through the trabecular meshwork and into Schlemm's canal. Advance in the direction of the trabecular meshwork to be cut by pivoting and advancing/ retracting the thin neck along the clear corneal incision while keeping the footplate in Schlemm's canal. Detach the trabecular meshwork strip by use of the KDB or microforceps. After cutting the trabecular meshwork, retract through the original clear corneal incision.	Inserted through a previously created clear corneal incision. The anterior chamber is maintained with irrigation fluid. Under gonioscopic evaluation, insert the tip through the clear corneal incision and advance to the opposite side of the anterior chamber. Engage the trabecular meshwork across from the clear corneal incision with the tip and penetrate the trabecular meshwork and advance along Schlemm's canal. Feed trabecular meshwork into the ablative bipolar electrodes as the tip advances along the Schlemm's canal. Aspirate to remove the trabecular meshwork. After cutting the trabecular meshwork, retract through the original clear corneal incision.
Viscoelastic	Separate viscoinjector used to stabilize anterior chamber	Separate viscoinjector used to stabilize anterior chamber
Materials	Stainless steel tip, stainless steel shaft and plastic handle	Stainless steel probe and ABS plastic handpiece
User Interface	Handheld	Handheld
Sterile andSingle Use	Yes	Yes
Sterility Assurance Level	10^{-6}	10^{-6}

VI. PERFORMANCE DATA

Bench Testing

The non-clinical bench testing performed on the Kahook Dual Blade Glide device consisted of design

verification and functional product testing, sterilization validation, packaging, shelf-life testing, and biocompatibility testing. Results of the non-clinical bench testing demonstrate that the Kahook Dual Blade Glide meets the defined specifications and functions as intended (see Table below). The Kahook Dual Blade Glide functional characteristics are well defined and sufficient to establish equivalence to the predicate device. The device was evaluated to verify the design outputs met the original design inputs and intent.

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
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}
Corrosion testing	ISO 13402 - Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion and thermal exposure	All samples met the acceptance criteria
Autoclave Testing	ISO 13402 - Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion and thermal exposure	Material's Heat Deflection Temperature shall be less than 121°C
Endotoxin Testing	ANSI/AAMI ST72 - Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices Guidance for Industry and Food and Drug Administration Staff	Routine monitoring All samples met the acceptance criteria
Shelf-Life Testing		
Visual Inspection	ASTM F1886	All samples met the acceptance criteria

Test Performed	Standard/Guidance	Results
	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection	
Seal Strength	ASTM F88 Standard Test Method for Seal Strength of Flexible Barrier Materials	All units had a seal strength above 0.75 lbf
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
Additional Testing		
Deflection test	Devices did not deflect under normal use	
Tensile Test	Devices passed the Tensile stress test	

VII. CLINICAL EVIDENCE

The reference device, OMNI Surgical System (K202678), was used to support the scientific methodology to evaluate the ability of KDB to reduce IOP in adult patients with POAG and a systematic literature review was performed to characterize the safety of the predicate device, NMX-1000.

KDB Glide Procedure Performed with Cataract Surgery (Falkenberry et al.)

Falkenberry S, Singh IP, Crane CJ, Haider MA, Morgan MG, Grenier CP et al. Excisional goniotomy vs trabecular microbypass stent implantation: a prospective randomized clinical trial in eyes with mild to moderate open-angle glaucoma. *J Cataract Refract Surg*. 2020; 46(8):1165–71.

Falkenberry et al. conducted a prospective, randomized, active-controlled, parallel group clinical trial of the KDB Glide procedure combined with cataract surgery. The study was conducted at 9 study sites in the U.S. and surgeries were performed between June 2016 and January 2019. The purpose of the study was to compare reduction in intraocular pressure (IOP) and IOP-lowering medication in eyes undergoing excisional goniotomy with Kahook Dual Blade (KDB) Glide vs iStent trabecular micro-bypass (Glaukos, Inc.) implantation, both combined with phacoemulsification, in eyes with mild-to-moderate open-angle glaucoma (OAG). This 510(k) summary focuses on the results of the KDB-phaco cohort only.

The study consisted of eyes diagnosed with open-angle glaucoma, including pseudoexfoliative glaucoma and pigmentary glaucoma. The KDB-phaco cohort consisted of 82 eyes of 82 subjects. The majority of study eyes (n = 75, 95.1%) had a diagnosis of primary open-angle glaucoma (POAG); 5 eyes (6.1%) had pseudoexfoliative glaucoma (PEG) and the remainder (n = 2, 2.4%) had pigmentary glaucoma (PG). The glaucoma severity was characterized as mild (79.3%) to moderate (20.7%). Subjects were followed for 12 months and were evaluated 1 day, 1 week, and 1, 3, 6, and 12 months postoperatively.

Baseline characteristics were as follows:

Baseline Characteristics	KDB-Phaco (N = 82)
Mean Age ± SD	70.2 ± 0.91 years
Sex	Female: 44 (53.7%) Male: 38 (46.3%)
Ethnicity	White: 66 (80.5%) African American: 10 (12.2%) Asian: 3 (3.7%) Hispanic: 1 (1.2%) Other: 2 (2.4%)
Medicated IOP Mean ± SD	18.5 ± 0.36 mmHg
Glaucoma Medications Mean ± SD	1.31 ± 0.07 meds
C/D Ratio	0.60 ± 0.018

The key inclusion criteria consisted of subjects 18-90 years of age with mild-moderate POAG, PEG, or PG who were on 1-3 topical ocular hypotensive medications. In order to qualify, subjects needed a baseline IOP of 14-28 mmHg (inclusive) and a visually significant cataract planned for elective extraction. Subjects using oral medications that could affect IOP, previous glaucoma surgery, recent (≤ 3 months) glaucoma laser therapy, closed angles, or a history of steroid response were identified as key exclusion criteria.

Under ophthalmic viscosurgical device and using a gonioprism for visualization, the KDB Glide was introduced through a clear corneal incision approximately 180° from the targeted excision site. The pointed tip of the device engaged trabecular meshwork (TM), with the heel positioned within Schlemm's canal and the blade was advanced to excise a strip of trabecular meshwork (TM) approximately 3-4 clock hours in length using the parallel blades of the device. The KDB Glide was then removed through the corneal incision.

The primary effectiveness endpoint was the proportion of eyes at 12 months with IOP reduction of 20% or greater or IOP medication reduction of 1 or more compared with baseline. Secondary effectiveness endpoints included the percentage reduction in IOP and the mean decrease in the number of IOP-lowering medications.

Of the 82 eyes treated with KDB-phaco, 79 eyes were available for the 12-month visit and 3 eyes were considered lost to follow-up. There were no eyes with glaucoma secondary surgical intervention (SSI) for IOP control during the 12-month study; therefore, the effectiveness analyses included all 79 available eyes. The proportion of eyes at 12 months with an IOP reduction of 20% or greater from baseline or IOP medication reduction of 1 or more medication from baseline was 93.7% (74/79 eyes). Mean (SD) IOP decreased from a baseline of 18.5 (0.4) mmHg to 15.4 (0.4) mmHg at 12 months. Mean (SD) IOP-lowering medications were reduced from 1.3 (0.1) at baseline to 0.3 (0.1) at 12 months.

Safety outcomes included corrected distance visual acuity loss by 2 lines or more from best recorded to final visit, operative complications, device malfunctions, IOP elevations of 10 mmHg or greater from baseline, and adverse events. The following adverse events were reported:

Adverse Event	KDB-Phaco (N = 82)
Increased IOP	26 eyes (31.7%)
Posterior Capsule Opacification	7 eyes (8.5%)
Hyphema	3 eyes (3.7%)

Adverse Event	KDB-Phaco (N = 82)
Cyclodialysis Cleft	1 eye (1.2%)

The most common adverse event was increased IOP, reported as occurring at least one postoperative visit in 26/82 (31.7%) eyes; these all resolved spontaneously or with medical management. Posterior capsule opacification (PCO) occurred in 7/82 (8.5%) eyes. Blood persisting in the anterior chamber beyond the first postoperative week (hyphema) occurred in 3/82 (3.7%) of study eyes. One eye (1.2%) developed a cyclodialysis cleft.

KDB Glide Procedure Performed Standalone (ElMallah et al.)

ElMallah MK, Berdahl JP, Williamson BK, Dorairaj SK, Kahook MY, Gallardo MJ et al. Twelve-month outcomes of stand-alone excisional goniotomy in mild to severe glaucoma. *Clin Ophthalmol*. 2020; 14:1891–97.

ElMallah et al. conducted a retrospective, multicenter case series of the KDB Glide performed as a standalone procedure. Data was collected from 8 surgeons at 8 study sites (6 in the U.S. and 2 in Mexico). The purpose of the study was to characterize the reductions in intraocular pressure (IOP) and IOP-lowering medication following excisional goniotomy with KDB Glide standalone in eyes with medically uncontrolled glaucoma.

The study enrolled 42 eyes of 35 subjects with no restrictions for glaucoma sub-type or severity. The majority of eyes had a diagnosis of primary open angle glaucoma (n = 36, 85.7%), but the study also included a small number of eyes diagnosed with pigmentary glaucoma (n = 3, 7.1%), pseudoexfoliative glaucoma (n =2, 4.8%), and angle-closure glaucoma (n = 1, 2.4%). Glaucoma severity was evaluated according to the International Classification of Diseases-10 (ICD-10) criteria, and was characterized as mild (19.0%), moderate (61.9%), or severe (19.0%). Subjects were followed for 12 months and were evaluated 1 day, 1 week, and 1, 3, 6, and 12 months postoperatively.

Baseline characteristics were as follows:

Baseline Characteristics	KDB-Standalone (N = 42)
Mean Age ± SE	71.3 ± 1.8 years
Sex	Female: 25 (59.5%) Male: 17 (40.5%)
Ethnicity	White: 19 (45.2%) Black: 13 (31.0%) Hispanic: 9 (21.4%) Asian: 1 (2.4%)
Medicated IOP Mean ± SE	21.6 ± 0.84 mmHg
Glaucoma Medications Mean ± SE	2.55 ± 0.22 meds

Included subjects were ≥ 18 years of age, phakic or pseudophakic, and with any glaucoma sub-type or severity. There were no baseline IOP requirements other than inadequate IOP control on at least 1 and up to 3 ocular hypotensive medications. Indication(s) for surgery included reducing IOP, reducing medication

burden, or both. Subjects with a recent history (within 3 months) of IOP-lowering medication addition, laser trabeculoplasty, iridotomy, or initiation of systemic beta-blocker therapy were excluded from the study. Other exclusion criteria included any previous glaucoma surgery, and uncontrolled systemic conditions that might confound study measurements. Both eyes of a single subject were included if both qualified.

Following entry into the anterior chamber through a peripheral corneal incision, the KDB Glide distal tip was used to pierce the trabecular meshwork (TM) and enter Schlemm's canal. The tip was advanced along the canal to elevate and guide the TM onto two parallel blades which then excise a strip of tissue. Approximately 3-5 clock hours of TM were excised.

The primary effectiveness endpoint was IOP reduction compared to baseline. The reduction in IOP-lowering medications was evaluated as the secondary effectiveness endpoint. Eyes with glaucoma secondary surgical intervention (SSI) for IOP control were excluded from the primary and secondary effectiveness analyses. Of the 42 eyes treated with KDB as a standalone procedure, 35 were available for the 12-month visit. Six eyes (n =6) required SSI for IOP control through 12 months and one eye (n =1) was considered lost to follow-up. At the 12-month visit, mean (SE) IOP was reduced by 3.94 (1.1) mmHg (n = 35). Mean (SE) number of IOP-lowering medications was reduced by 0.31 (0.23) at 12 months (n = 35).

In addition to the primary and secondary endpoints, ElMallah et al. report additional effectiveness outcomes for all treated eyes (N = 42) where eyes requiring SSI (n = 6) and the eye that was lost to follow-up (n = 1) were counted as failures. These additional analyses included the proportion of eyes with an IOP reduction of 20% or greater compared to baseline which was 42.9% (18/42 eyes).

Safety reporting consisted of the incidence of intraoperative and postoperative adverse events. The following adverse events were reported:

Adverse Event	KDB Standalone (N = 42)
Increased IOP	3 eyes (7.1%)
Descemet's tear (intraoperative)	1 eye (2.4%)

The most common adverse event was postoperative elevated IOP (n = 3, 7.1%). One case resolved with medical therapy, and the other two required a secondary surgical intervention. One eye experienced an intraoperative tear in Descemet's membrane, which was localized and did not require subsequent treatment during the 12-month study. No other adverse events were reported. Over the course of 12 months, 6 eyes required additional surgeries for inadequate IOP control. These included trabeculectomy (n = 4; 2 of which had concurrent Ex-Press mini-shunt) and Ahmed valve implantation (n = 2).

Conclusion

The non-clinical and clinical data demonstrate that the device is substantially equivalent to the legally marketed predicate device, NMX-1000.

VIII. SUBSTANTIAL EQUIVALENCE CONCLUSIONS

The indications for use of the Kahook Dual Blade Glide fall within the intended use of the NeoMedix predicate device and, therefore, the two devices have the same intended use. Although the operating principle differs, there are no particular technological aspects of the Kahook Dual Blade Glide (manual cutting to remove trabecular meshwork) that were not evaluated in the context of the premarket review for

the predicate device (bipolar electro-surgical pulse to remove trabecular meshwork). Specifically, a manual operating principle raises the same or fewer questions related to safety and effectiveness as compared to an electrosurgical operating principle for the same intended use; therefore, there are not different types of safety and effectiveness questions related to the simpler technological characteristics of the Kahook Dual Blade Glide.

The Kahook Dual Blade Glide meets all product design requirements and applicable device standards. The conclusions drawn from the nonclinical and clinical performance data demonstrate that the Kahook Dual Blade Glide is substantially equivalent to the predicate device for the same intended use.