May 9, 2023

C. Light Technologies, Inc.
℅ Christy Coleman
Regulatory Consultant
Blur Product Development
260 James Jackson Avenue
Cary, North Carolina 27513

Re: K222484
Trade/Device Name: Retitrack
Regulation Number: 21 CFR 886.1510
Regulation Name: Eye Movement Monitor
Regulatory Class: Class II
Product Code: HLL
Dated: March 31, 2023
Received: April 3, 2023

Dear Christy Coleman:

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,

Elvin Y. Ng -S

Elvin Ng
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)*
K222484

Device Name
Retitrack

Indications for Use *(Describe)*
The Retitrack™ is intended for recording, viewing, measuring, and analyzing temporal characteristics of fixation and saccadic responses when viewing a visual stimulus. The Retitrack™ is intended for use by healthcare practitioners in healthcare settings (e.g., physician's office, clinic, laboratory).

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.

510(k) SUMMARY

Preparation Date:	May 8, 2023
Submitter:	C. Light Technologies, Inc. 84 High St., Suite 303 Medford, MA 02155 Contact: Christy K. Sheehy-Bensinger, Ph.D., CEO Phone: 518-339-2895
Device Information:	
Trade Name:	Retitrack™
Common/Classification Name:	Eye Movement Monitor
Device Classification:	Class II (21 CFR 886.1510)
Product Code:	HLL
Predicate Device:	Saccadometer Plus (K152890) Class II (21 CFR 886.1510); Product Code HLL Applicant: Ober Consulting Sp. Z.o.o.
Reference Devices:	RightEye Vision System (K181771) Class II (21 CFR 882.1460); Product Code GWN Applicant: RightEye LLC
	CenterVue COMPASS (K150320) Class II (21 CFR 886.1570); Product Codes MYC and HPT Applicant: CenterVue S.p.A.

Device Description:

The Retitrack™ is a monocular, bench-top saccadometer that incorporates scanning laser ophthalmoscope (SLO) technology and eye tracking software to record, view, measure, and analyze eye motion. The Retitrack™ is comprised of an optical head containing an illumination system and an optical system; a base unit with a computer, electronics, and a power distribution system; connections for external input/output devices (e.g., monitor, keyboard, mouse, and storage media); a patient forehead and chin rest; and operational software.

The Retitrack™ interacts with the patient by directing light from an infrared (840 nm) superluminescent diode (SLD) into the patient's eye. The only parts of the device that contact the patient are the forehead and chin rest with adjustable temple pads and an optional attachable head strap to stabilize the patient's head.

The Retitrack™ uses the SLD light to scan the patient's retina in two dimensions while the patient is viewing a visual stimulus. The optical imaging system detects the reflected (or returned) light from the retina and creates high-resolution, digital retinal video sequences over time. The eye tracking software uses eye motion corrected frames to measure the translational retinal movement over time. The device displays the analysis of the eye motion results and saves the retinal video and a report. The Retitrack™ does not provide a diagnosis or treatment recommendation.

The Retitrack™ has separate tests that measure fixation stability (including microsaccades and drift) and visually guided horizontal saccade tracking. The Retitrack™ can be programmed by the user with specific visual stimuli presentations, including a single fixed stimulus to measure fixation stability or two alternating stimuli in different orientations to measure horizontal saccades. For the fixation stability test, the Retitrack™ analyzes the fixation responses, including microsaccade amplitude, microsaccade frequency, microsaccade velocity, drift velocity, and drift ratio over time. For the saccade tracking tests, the Retitrack™ analyzes the saccadic responses, including duration, amplitude, target accuracy, latency, and velocity.

The Retitrack™ is classified as a Group 1 scanning instrument, which poses no potential light hazard during device operation, per the American National Standards Institute (ANSI) Z80.36-2021, *Light Hazard Protection for Ophthalmic Instruments* standard. In addition, the Retitrack™ is classified as a Class 1 laser product per the International Electrotechnical Commission (IEC) 60825-1:2014 (Ed 3.0) *Safety of laser products – Part 1: Equipment classification and requirements* standard.

Intended Use/Indications for Use:

The Retitrack™ is intended for recording, viewing, measuring, and analyzing temporal characteristics of fixation and saccadic responses when viewing a visual stimulus. The Retitrack™ is intended for use by healthcare practitioners in healthcare settings (e.g., physician's office, clinic, laboratory).

The Retitrack™ has the same intended use as the predicate device to measure and record temporal characteristics of saccadic responses when viewing a visual stimulus.

Comparison of Technological Characteristics:

The Retitrack™ shares many of the same technological characteristics as the Saccadometer Plus. Both the Retitrack™ and the predicate device direct infrared light into the eye and use the reflected light to track the eye for the purpose of measuring eye movement. Although their light sources are different, both devices conform to voluntary consensus standards for light safety and laser safety.

The Retitrack™ device tracks eye movement by measuring the translational retinal movement observed between video frames over time, whereas the predicate device tracks eye movement based on anterior eye landmarks. The method of retinal tracking to measure eye movement is substantiated by the COMPASS reference device, which uses retinal tracking to measure fixation stability.

While the temporal resolution of the Retitrack™ differs from the predicate device, the published literature on the temporal resolution needed to track fixational and saccadic movements along with the temporal resolution of the reference devices reflect that this difference does not raise new or different questions of safety or effectiveness.

The Retitrack™ collects monocular eye movement data while the predicate device collects binocular data. Due to the conjugacy and synchronicity of saccadic eye movements, the predicate device adds and averages the data for both eyes. Therefore, the difference between monocular and binocular data collection does not affect the effectiveness to measure saccades.

Both the Retitrack™ and the predicate device measure visually-guided horizontal saccades using multiple displaced visual stimuli to generate eye movements. The Retitrack™ has additional functionality to measure fixational stability, which is also measured by the RightEye reference device.

The Retitrack™ uses an internal monitor to display visual stimuli to generate eye movements, similar to the RightEye reference device, and corrects for the patient's refractive error, similar to the COMPASS reference device. Conversely, the predicate device presents visual stimuli using laser projectors that are mounted to the forehead and does not provide refractive error correction. These differences do not affect the ability of the device to present visual stimuli to generate eye movement and accurately measure saccadic responses. Therefore, these differences do not raise new or different safety and effectiveness questions.

Both devices record, analyze, and report temporal characteristics of eye movements and use software algorithms to detect saccades. The Retitrack™ has integrated software with a graphical user interface used to record, view, measure, and analyze eye movement, whereas the predicate device has separate hardware to record movement and software to analyze the data. The difference in integrated vs. separate hardware/software applications does not affect the effectiveness of the device to record, view, or analyze data. In addition, both the RightEye and COMPASS reference devices provide a software user interface like the Retitrack™.

Both the Retitrack™ and the predicate device contact the patient's intact skin/hair over a limited contact duration and are designed to be biocompatible for their intended use. Additionally, both devices conform to consensus standards for electrical safety and electromagnetic compatibility (EMC). The conformance to these standards supports that the difference between the AC-power of the Retitrack™ vs. battery power of the predicate device does not raise new or different safety questions.

The technological differences between the Retitrack™ and the predicate device are substantiated by similar technological characteristics in the technological reference devices. Furthermore, the technological differences do not raise new or different questions of safety and effectiveness, as demonstrated by performance testing of the Retitrack™ device.

Table 1 compares the Retitrack™ with the predicate and reference devices.

Table 1. Predicate and Reference Device Comparison Table				
Feature	**PROPOSED SUBJECT DEVICE Retitrack™**	**PREDICATE DEVICE K152890 Saccadometer Plus**	**REFERENCE DEVICE K181771 RightEye Vision System**	**REFERENCE DEVICE K150320 COMPASS**
Device and Product Code Classification	Eye Movement Monitor (HLL) 21 CFR 886.1510, Class II	Eye Movement Monitor (HLL) 21 CFR 886.1510, Class II	Nystagmograph (GWN) 21 CFR 882.1460, Class II	Ophthalmoscope, Laser Scanning and Perimeter (MYC and HPT) 21 CFR 886.1570, Class II 21 CFR 886.1605, Class I
Intended Use/ Indications for Use	The Retitrack™ is intended for recording, viewing, measuring, and analyzing temporal characteristics of fixation and saccadic responses when viewing a visual stimulus.	The Saccadometer Plus is intended for measuring temporal characteristics of saccadic refixation responses when viewing lateral visual stimulus and identifying the individual time delays of moving the eyes toward the stimuli.	The RightEye Vision System is intended for recording, viewing, and analyzing eye movements in support of identifying visual tracking impairment in human subjects.	The CenterVue COMPASS is intended for taking digital images of a human retina without the use of a mydriatic agent and for measuring retinal sensitivity, fixation stability and the locus of fixation. It contains a reference database that is a quantitative tool for the comparison of retinal sensitivity to a database of known normal subjects.
Rx Only/OTC	Prescription Device	Prescription Device	Prescription Device	Prescription Device
Eye Movement Tracking Method	• Analyzes reflected infrared light to track eye movements • Retinal Tracking • Pupil camera used for alignment purposes	• Analyzes reflected infrared light to track eye movements • Anterior eye (corneal bulge, limbus, iris/pupil) tracking • Fixation target used to define the initial eye position	• Analyzes reflected infrared light to track eye movements • Pupil tracking • Includes a remote camera	• Analyzes reflected infrared light to track eye movements • Retinal Tracking • Pupil camera used for alignment purposes
Performance Specifications	Spatial Resolution: < 1.2 arc min Temporal Resolution: 480 Hz	Spatial Resolution: < 5 arc min Temporal Resolution: 1,000 Hz	Spatial Resolution: Unknown Temporal Resolution: 60 Hz	Spatial Resolution: Unknown Temporal Resolution: 25 Hz
Eye Movement Measurements	• Monocular • Visually Guided Horizontal Saccades • Fixational Stability	• Binocular (added and averaged) • Visually Guided Horizontal Saccades	• Binocular • Visually Guided Horizontal and Vertical Saccades • Fixational Stability	• Monocular • Fixational Stability
Visual Stimuli to Generate Eye Movement	• Built-in stimulus presentation using a display monitor • User can program specific stimuli presentations/durations ○ Multiple displaced stimuli ○ Horizontal position ○ Single center fixed target • Refractive error compensation	• Built-in stimulus presentation using laser projectors • User can program specific stimuli presentations/durations ○ Multiple displaced stimuli ○ Horizontal position ○ Center fixed target	• Stimulus presentation using monitor as projection source • User can program different stimuli presentations ○ Multiple displaced stimuli ○ Horizontal/vertical position ○ Single fixed target	• Fixation target projector projects green LED target • User cannot program different stimuli presentations ○ Single fixed target • Refractive error compensation

Table 1. Predicate and Reference Device Comparison Table				
Feature	**PROPOSED SUBJECT DEVICE Retitrack™**	**PREDICATE DEVICE K152890 Saccadometer Plus**	**REFERENCE DEVICE K181771 RightEye Vision System**	**REFERENCE DEVICE K150320 COMPASS**
Software and Data Analysis	• Automatic saccade detection algorithm • Software records, views, and analyzes eye movement data • Graphical User Interface	• Automatic saccade detection algorithm • Separate software application (LatencyMeter) views and analyzes eye movement data	• Automatic saccade detection algorithm • Software records, views, and analyzes eye movement data • Graphical User Interface	• Analysis of fixation characteristics, allowing active compensation of the position of perimetric stimuli • Graphical User Interface
Eye Movement Measurement Output	• Latency (promptness) • Duration • Velocity • Amplitude (Position) • Target accuracy • Fixation Stability	• Latency (promptness) • Duration • Velocity • Amplitude (Position)	• Latency (promptness) • Duration • Velocity • Amplitude (Position) • Target accuracy • Fixation Stability	• Fixation stability
Patient Contact Components	• Biocompatible for limited duration, intact skin/hair contact • Cleaned with medical grade disinfectant wipe	• Biocompatible for limited duration, intact skin/hair contact • Cleaned with medical grade disinfectant wipe	Not applicable – no patient contact	• Biocompatible for limited duration, intact skin contact • Cleaned with medical grade disinfectant wipe
Light Safety	• Infrared (840nm) Superluminescent Diode (SLD) • Complies with ANSI Z80.36-2021 for Group 1 scanning instruments (weighted power ≤ 1.32 mW at the eye) • Class 1 Laser (finished device) complies with IEC 60825-1:2014	• Infrared (940 nm) LED (irradiance <1mW/cm2) • Complies with IEC 62471 standard for light safety • Class 2 lasers, 655 nm, <1mW • Complies with IEC 60825-1:2007 for laser safety	• Near infrared light source • Complies with IEC 62471	• Infrared (825-870 nm) imaging system with scanning mirror • Infrared LEDs and visible (440-650) LED illumination sources • Complies with ISO 15004-2:2007 for light hazard protection
Electrical Safety/ Electromagnetic Compatibility (EMC)	• AC-powered • Complies with IEC 60601-1 and IEC 60601-1-2	• Battery-powered • Complies with IEC 60601-1 and IEC 60601-1-2	• AC-powered • Complies with IEC 60601-1 and IEC 60601-1-2	• AC-powered • Complies with IEC 60601-1 and IEC 60601-1-2

Performance Testing:

The following non-clinical performance testing was conducted for the Retitrack™:

- Verification of compliance to the following standards:
  - IEC 60601-1:2005 + AMD1:2012 + AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
  - IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
  - IEC 60825-1:2014 Safety of laser products – Part 1: Equipment classification and requirements
  - ANSI Z80.36-2021 Ophthalmics - Light Hazard Protection for Ophthalmic Instruments

- Software verification and validation testing of the function, graphical user interface, analysis algorithm, and usability with representative intended users in a simulated use environment.

- Bench performance testing for verification of:
  - Eye movement measurement accuracy and tracking performance;
  - Optical subsystem and visual stimulus/fixation display performance;
  - Mechanical and electrical hardware safety and reliability; and
  - Performance under environmental operating, storage, and transport conditions.

The following performance testing was conducted using human subjects to evaluate the performance of the Retitrack™ to measure and analyze eye movements:

- The intended use for recording, viewing, measuring, and analyzing the temporal characteristics of fixation and saccadic responses when viewing a visual stimulus was validated using 21 human subjects (ages 21-55). This sample contained 10-second human eye movement videos with > 200 videos for fixation stability and > 300 videos for horizontal saccade tracking. Fixation and saccade measurements were successfully measured for all subjects. Furthermore, a linear relationship with an excellent correlation was found between the expected response and the measured retinal response for the saccade amplitude and velocity measurements.

- A comparison of retinal and pupil tracking methods was performed using 21 human subjects (ages 19-53). For each subject, 10-second retinal videos were recorded with the Retitrack™, while pupil videos were recorded simultaneously with the alignment camera. The pupil videos were processed with a standalone pupil tracking algorithm. Measurements of horizontal saccades at different stimulus target separations were performed with the analysis of amplitude, latency, and velocity. Linear regression and agreement analyses demonstrated good agreement between the pupil and retinal tracking methods for saccade amplitude, latency, and velocity measurements.

The testing showed that the velocity measurement is, on average, 1.5 times (95% CI of 1.2 to 1.8 times) faster with the Retitrack™ (sampling at temporal resolution of 480 Hz) as compared to a conventional pupil-based eye tracking system (sampling at a temporal resolution of 60 Hz). This information was updated accordingly in the Instructions for Use to inform users how to compare the Retitrack™ to other pupil-based tracking methods.

Conclusions:

Performance testing demonstrated that the Retitrack™ meets all design requirements for safety and performance. Performance testing validated the Retitrack™ for its intended use and demonstrated that retinal tracking is an equivalent method to anterior eye/pupil tracking for measurement of saccadic responses.

Based on the collective performance test results, the Retitrack™ is as safe and effective as the predicate device for the intended use. In conclusion, C. Light Technologies, Inc. has demonstrated that the Retitrack™ is substantially equivalent to the predicate device in intended use and technological characteristics.