May 31, 2024

Evolution Optiks Limited
% John Smith
Partner
Hogan Lovells US LLP
555 13th Street NW
Washington, District of Columbia 20004

Re: K233295
Trade/Device Name: LFR-260
Regulation Number: 21 CFR 886.1770
Regulation Name: Manual Refractor
Regulatory Class: Class I
Product Code: SBI
Dated: May 3, 2024
Received: May 3, 2024

Dear John Smith:

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,

Elvin Y. Ng -S

Elvin Ng
Assistant Director
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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)*
K233295

Device Name
LFR-260 System

Indications for Use *(Describe)*
The LFR-260 is a portable manual refractor providing capabilities to the eyecare provider to perform distance vision testing and subjectively measure sphere, cylinder and axis refractive errors in patients aged from 12-65 years old with healthy visual systems. The device measures spherical error in the range of -10 to +15D and measures cylinder error within +/- 2.5D.

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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**510(k) SUMMARY**

**Evolution Optiks LFR-260 System**

**Submitter**

**Evolution Optiks Limited**

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Date Prepared: May 30, 2024

## 1. Device Information

**Name of Device:** LFR-260 System

**Common or Usual Name:** Manual Refractor

**Classification Name:** Manual Refractor

**Regulation Number:** 21 C.F.R. 886.1770

**Product Code:** SBI

**Regulatory Class:** Class I

## 2. Predicate Device Information

**510(k) number** K936205

**Trade name:** Comprehensive Phoropter, MDR-680

**Classification Name:** Manual Refractor

**Regulation Number:** 21 C.F.R. 886.1770

## 3. Device Description

The LFR-260 is a portable digital refractor which allows for determination of refractive error as well as for fully remote refractions. The LFR-260 achieves the similar functionality as Comprehensive

Phoropter, MDR-680, which is a standard refractor, but relies on the use of a micro lens array, a high-density embedded display, and a tunable lens. The reduced number of lenses allows for higher portability and a smaller footprint.

The LFR-260 system is able to perform the same distance vision traditional refractive test with the standard optotypes (Snellen, ETDRS, Landolt C, pediatric optotypes) as a standard refractor, such as:

- Determining the required spherical correction
- Determining the required astigmatic correction measuring with fan and block test and/or JCC (Jackson cross-cylinder)

The visual acuity tests will always be administered by an eye care practitioner licensed and registered by the appropriated body in the region intended to be used.

## 4. Intended Use / Indications for Use

The LFR-260 is a portable manual refractor providing capabilities to the eyecare provider to perform distance vision testing and subjectively measure sphere, cylinder and axis refractive errors in patients aged from 12-65 years old with healthy visual systems. The device measures spherical error in the range of -10 to +15D and measures cylinder error within +/- 2.5D.

## 5. Summary of Technological Characteristics

The intended use of LFR-260 is consistent with Comprehensive Phoropter, MDR-680, which is a manual refractor. The substantial equivalence table is provided below:

| | LFR-260 | Comprehensive Phoropter, MDR-680 | Discussion |
|---|---|---|---|
| Technological Characteristics | The LFR-260 system includes a micro lens array, tunable lenses, and high pixel-density display to provide the same functionality as a traditional reel of lenses to allow the measure of refractive error of the eye. | The Comprehensive Phoropter, MDR-680, is a manual refractor and is defined as a device that is a set of lenses of various dioptric powers intended to measure the refractive error of the eye. | Differences in technological characteristics do not raise different questions of safety and effectiveness. Performance data demonstrates comparable performance and safety. |
| Overview of Device | The LFR-260 is a portable manual refractor providing capabilities to the eyecare provider to perform distance vision testing and subjectively measure sphere, cylinder and axis refractive errors in patients aged from 12-65 years old with healthy visual systems. | The Comprehensive Phoropter, MDR-680 is regulated under 886.1770, primary product code HKN. A manual refractor, which is a device that is a set of lenses of various dioptric powers intended to measure the refractive error of the eye. | Both devices are intended to measure refractive error of the eye. |
| Operation/Tests Available | The LFR-260 device provides similar subjective | As a manual refractor, the comprehensive phoropter | Substantially similar. Both |

| | | | |
|---|---|---|---|
| | refraction as manual refractors including sphere, cylinder, and axis measurements.<br>The LFR-260 can be used to administer comparable eye examination that is standard of care in eye care professionals' clinics. Specifically, the LFR-260 is able to perform comparable traditional refractive tests with the standard optotypes (e.g., Snellen, ETDRS, Landolt C, pediatric optotypes) such as:<br>• Determining the required spherical correction<br>• Determining the required astigmatic correction measuring with fan and block test and/or JCC (Jackson cross-cylinder) | MDR-680 provides subjective refraction including sphere, cylinder and axis measurements. It can be used to administer the eye examination that is standard in eye care professionals' clinics.<br><br>Manual refractors can perform traditional refractive tests such as:<br>• Determining the required spherical correction<br>• Determining the required astigmatic correction measuring | systems provide examinations to measure refractive error of the eye. The LFR-260, however is indicated for distance vision testing only. |
| Type of Display | High pixel-density display | Traditional screen is used to display eye charts | A high pixel-density display is used to view the eye charts with the subject device while a traditional screen is used with manual refractors. Though there are technological differences, both displays provide users with eye charts for use during a routine eye examination. There are no new questions of safety or effectiveness due to this difference. |
| Type of Lenses | Tunable Lenses | Traditional reel of lenses | Both types of lenses enable the devices to perform subjective refractive tests. There are no new questions of safety or effectiveness due to this difference. |

| | | | |
|---|---|---|---|
| Included Software | Proprietary Software used to control the LFR-260 system by an ECP | No software required | The software controls the LFR-260 to achieve its intended use. There are no new questions of safety or effectiveness. |
| Use Environment | Professional Healthcare Facility Environment/Optometric Clinics,<br>Home Healthcare Environment | Professional Healthcare Facility Environment/Optometric Clinics | Differences in use environment do not impact the intended use of the device.<br>There are no new questions of safety or effectiveness. Performance data demonstrates comparable performance and safety. |
| Intended User | Licensed eye care practitioner | Licensed eye care practitioner | Same |

## 6. **Performance Data**

Both bench and clinical testing were performed to demonstrate that LFR-260 performs safely and effectively in achieving its intended use.

The LFR-260 underwent bench testing to evaluate the following characteristics:

- Visual acuity chart or display with specified size, distance, and range of acceptable luminance based on the standard of ANSI Z80.21-2020.
- Lenses to measure refractive error.
- Jackson Cross Cylinder (JCC) unit.
- Inter-Pupillary Distance (IPD).

Additionally, the system was evaluated to ensure it is able to produce both double and quad view and the ability of the cooling system to maintain the temperature of the tunable lenses.

In all instances, LFR-260 functioned as intended and each test's pre-specified success criteria were met.

The company also performed clinical testing to demonstrate comparability of the device's refractive measurements to the predicate device.

Based on Bland Altman analysis, in three subgroups (<=21, 22-40 and 40-60 years of age), the measurements were within 95% Limits of Agreement (LOA), defined as 0.75D for M and 0.5D for J0 and J45 (-0.52D to 0.41D for M, -0.3 to +0.23 for J0 and -0.13 to +0.13 for J45).
Precision testing was also performed. All sub-tests indicated acceptable repeatability and reproducibility.

Based on the clinical performance as documented in the pivotal clinical study, the LFR-260 has a safety and effectiveness profile that is similar to Comprehensive Phoropter, MDR-680.

## 7. **Conclusions**

The LFR-260 system and a manual refractor have the similar intended use, performs the similar examinations, and provides the same output. Both systems are used by a licensed eye care practitioner. The outputs of the LFR-260 are the same as a traditional refraction exam performed using a manual refractor. Even though there are technological differences, these differences do not raise different questions of safety and effectiveness as demonstrated through bench and clinical testing. Thus, the LFR-260 is substantially equivalent to Comprehensive Phoropter, MDR-680.