August 30, 2023

Phoenix Innovative Healthcare Manufacturers Pvt. Ltd.
Michael Stuart
CFO
EL-209, Shil Mahape Road Electronic Zone;
MIDC TTC Industry Area, Mahape
Navi Mumbai, Maharashtra 400710
India

Re: K231123
Trade/Device Name: Phoenix Contact Lens Case - dome top flat pack (CL-01); Phoenix Contact Lens Case - classic flat pack (CL-02); Phoenix Contact Lens Case - sunglass shape flat pack (CL-03)
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (Hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LRX
Dated: April 20, 2023
Received: July 24, 2023

Dear Michael Stuart:

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,

Bennett N. Walker -S

Digitally signed by Bennett N. Walker -S
Date: 2023.08.30 09:57:47 -04'00'

for Angelo Green
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.

Submission Number *(if known)*

K231123

Device Name

Phoenix Contact Lens Case - dome top flat pack (CL-01);
Phoenix Contact Lens Case - classic flat pack (CL-02);
Phoenix Contact Lens Case - sunglass shape flat pack (CL-03)

Indications for Use *(Describe)*

Phoenix Contact Lens Case is indicated for storage of soft (hydrophilic), rigid gas permeable and hard contact lenses during chemical disinfection.

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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Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Phoenix Innovative Healthcare Manufacturers Private Limited
Applicant Address	EL-209, Shil Mahape Road Electronic Zone; MIDC TTC Industry Area, Mahape Navi Mumbai Maharashtra 400710 India
Applicant Contact Telephone	9548804274
Applicant Contact	Mr. Michael Stuart
Applicant Contact Email	mikes@phoenix-hs.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Phoenix Contact Lens Case - dome top flat pack (CL-01); Phoenix Contact Lens Case - classic flat pack (CL-02); Phoenix Contact Lens Case - sunglass shape flat pack (CL-03)
Common Name	Contact Lens Case
Classification Name	Opthalmic
Regulation Number	886.5928
Product Code	LRX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K112832	Optego/Eye Care Cure	LRX
K013232	Bausch & Lomb	LRX

Device Description Summary

21 CFR 807.92(a)(4)

There are three models of the Phoenix Contact Lens Case:

CL-01 "Dome Top Flat Pack" - made with LDPE and has 1.5ml wells on each side
CL-02 "Classic Flat Pack" - made with LDPE and has 1.5 ml wells on each side
CL-03 "Sunglass Shape Flat Pack" made with Polypropylene and has 2.0 ml wells on each side

All three models have hinged self sealing caps and are available in white, black, blue, orange, green, and natural.

The Phoenix contact lens cases are intended for storage during chemical disinfection of soft, rigid gas permeable or hard contact lenses. It is not to be used with heat disinfection.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Phoenix Contact Lens Case is indicated for storage of soft (hydrophilic), rigid gas permeable and hard contact lenses during chemical

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use are the same.

Technological Comparison 21 CFR 807.92(a)(6)

The proposed device has the same classification and product code as the predicate devices. The proposed device has the same intended use as the predicate devices. The proposed device has a similar design and is made of similar materials to the predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The nonclinical tests submitted were:

Cytotoxicity per ISO 10993-5
Intracutaneous skin irritation per ISO 10993-23
Guinea pig maximization (GPMT) skin sensitization per ISO 10993-10
Acute systemic injection per ISO 10993-11
Material mediated pyrogenicity per USP <151>
Acute ocular irritation testing per ISO 10993-23

The tests concluded the following:

Based on the results obtained under laboratory testing conditions, the extract of test item, Contact Lens Case was found to be “non-cytotoxic” to the subconfluent monolayer of L-929 mouse fibroblast cells.

Based on the above results of the experiment, it is concluded that the polar and non-polar extracts of Contact Lens Case was found to be “Non-sensitizer” to the skin of the Guinea pigs under the experimental conditions employed.

Based on the results of the experiment, it is concluded that the polar and non-polar extracts of test item, Contact Lens Case was “Non-irritant” to the skin of New Zealand White Rabbits under the experimental conditions and the dose employed as per the ISO 10993 Part 23:2021 (E) Specification.

Based on the results of the experiment, it is concluded that the polar and non-polar extracts of test item, Contact Lens Case when administered to Swiss Albino Mice through intravenous and intraperitoneal routes respectively at a dose volume of 50 mL/kg body weight did not reveal any systemic toxicity under the experimental conditions employed.

Based on the results of the experiment, it is concluded that the extract of test item, Contact Lens Case evaluated for pyrogen test in New Zealand White Rabbits is Non-pyrogenic as it meets the requirements of pyrogen test as per U.S. Pharmacopoeia, and General Chapters: <151> Pyrogen Test.

Under the experimental conditions employed and based on the observed results of the experiment, it is concluded that the polar and non-polar extract of test item, Contact Lens Case did not produce any irritant effects to the eyes of New Zealand White Rabbits as per ISO 10993 “Biological Evaluation of Medical Devices” Part 23:2021(E) “Test for Irritation”.

All testing demonstrates substantial equivalence.