K120904

RELIANCE

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510(k) Summary

(per 21 CFR 807.92)

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FDA Establishment Registration #: 3008388282

Date Prepared
February 10th, 2012

Trade Name
Polaris Dial-a-Date Contact Lens Case

Classification Name
Soft (hydrophilic) contact lens care products

Regulation Number
886.5928

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Product Code
LRX

Classification Panel
Ophthalmic Devices

Device Class
Class 2

Predicate Devices
Polaris Contact Lens Case (K093377) from Reliance Design & Manufacture Corp.

Intended Use
The Polaris Dial-a-Date Contact Lens Case is intended for the storage of soft (hydrophilic), rigid gas permeable, and/or hard contact lenses. Used for storage during chemical disinfection only. Not for use during heat disinfection.

Device Description
The Polaris Dial-a-Date contact lens case is a device for the storage of soft (hydrophilic) and rigid gas permeable contact lenses. Contact lenses can be fully immersed into the chamber and accommodates all lenses currently being sold in the market.
The contact lens case consists of a molded dual compartment bottom base and two screw-down lids. The bottom of each compartment is marked with L (left) and R (right).
The lids are also labeled with L (left) and R (right), and include a dial with molded-in numbers from 0 to 3 and 0 to 9, respectively. The outer lids are colored to make the molded-in numbers of the dials visible at the 'dialed position'. The dials can be incrementally rotated to let the user set reminders (i.e. day of the month to replace the contact lenses).
The outer lids and number dials do not come into contact with the lens care solution.

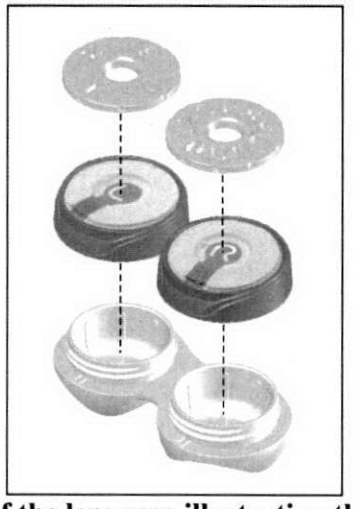

Figure 5A Exploded View of the lens case illustrating the coloring of the Outer Lid

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Comparison of Technological Characteristics

The following table compares the Polaris Dial-a-Date to the POLARIS (201) with respect to intended use, technological characteristics and principles of operation.

Table 5A – Comparison of Characteristics

Manufacturer	Reliance Design & Manufacture Corp.	Reliance Design & Manufacture Corp.
Product Name	POLARIS (201) Contact Lens Case	Polaris Dial-a-Date (202) Contact Lens Case
510(k) Number	K093377	Pending
Classification Advisory Committee	Ophthalmic	Ophthalmic
Product Code	LRX	LRX
Regulation #	886.5928	886.5928
Class	2	2
Intended Use	For storage of soft (hydrophilic), rigid gas permeable, and hard contact lenses. Use for storage during chemical disinfection only. Not for use during heat disinfection.	For storage of soft (hydrophilic), rigid gas permeable, and/or hard contact lenses. Use for storage during chemical disinfection only. Not for use during heat disinfection.
Composition (%)	- Polyolefin > 95% - Mixture < 5%	- Polyolefin > 95% - Mixture < 5%
Size	Length: 67.97mm Width: 31.97mm Height: 21.50mm	Length: 69.50mm Width: 33.50mm Height: 18.91
Volume	3.0 ml each side	4.4 ml each side
Number of Outer Lid Colors	Four (4)	Four (4)

Summary of Differences

The Polaris Dial-a-Date Contact Lens Case differs from its predicate device POLARIS (201) in some aspects that however do not affect its safety or performance.
The differences are as follows:

a) the Polaris Dial-a-Date (202) has a moveable part on the top lid to set a reminder while the predicate device POLARIS (201) has a plain top
b) the dimensions length, height and width differ slightly
c) the compartment volume is larger: 4.4 ml vs. 3.0 ml

Summary of Non-Clinical Data Submitted

The following testing has been performed to support substantial equivalence:

- Biocompatibility Testing according to the applicable standards, as described in Section 15 Biocompatibility
- Leakage Testing, as described in Section 18 Performance Testing – Bench Studies

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Biocompatibility Testing
The Polaris Dial-a-Date contact lens case has been evaluated for biocompatibility in accordance with Part 10993 of the ISO Standard tests, which include:

- ISO 10993-5:1999, Biological evaluation of medical devices -- Part 5: Tests for In Vitro Cytotoxicity.
  The test article did not induce cytotoxic effects and did not inhibit cell proliferation after being exposed for 24 to 48 hours in L929 colorectal carcinoma cells

- ISO 10993-10:2006, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity (Skin Sensitization).
  Under the conditions of this study, the test article extracted by Sodium Chloride 0.9% Inj. showed no evidence of causing delayed dermal contact sensitization in guinea pigs.

- ISO 10993-10:2006, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity (Ocular Irritation).
  All grades of ocular irritation calculated by maximum average score were zero. Based on the conditions and results of the study, the test article extract administered to NZW rabbits by ocular instillation did not cause any observable irritation response in vivo. All data generated from this study will provide as safety reference for human exposure.

- ISO 10993-11:2006, Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity.
  Under the conditions of this study, there was no mortality or evidence of systemic toxicity from the test article extract injected into ICR mice. All data generated from this study will provide as safety criteria for human exposure.

- ISO 10993-12:2007, Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials. (Biocompatibility).

Leakage Testing
Production units of the Polaris Dial-a-Date contact lens case have undergone leakage testing
The Polaris Dial-a-Date contact lens case was tested for leakage following a written test protocol. 192 combinations of different tops and bottoms were filled to 2/3 with liquid. Each set was turned upside down for 15 minutes and the tests were repeated 3 times. None of the tested lens cases showed any leakage and all of the Leakage Tests passed successfully. The results were documented

The Polaris Dial-a-Date Contact Lens Case complies with the voluntary standards as detailed in Section 9 Declarations of Conformity and Summary Reports of this submission.

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Safety and Effectiveness

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or has the same intended use and different technological characteristics, and it can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the differences between the Polaris Dial-a-Date Contact Lens Case and the predicate device do not raise any questions regarding its safety and effectiveness. The Polaris Dial-a-Date Contact Lens Case, as designed and manufactured, therefore is determined to be substantially equivalent to the referenced predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 26, 2012

NOV 2 6 2012

Reliance Design and Manufacture Corp.
% Ms. Caroline Tontini
International Project Manager
Emergo Group, Incorporated
611 West 5th Street, Third Floor
Austin, TX 78701

Re: K120904
Trade/Device Name: Polaris Dial-a-Date Contact Lens Case
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LRX
Dated: October 22, 2012
Received: October 31, 2012

Dear Ms. Tontini:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K120904

Indications for Use Statement

510(k) Number (if known): K120904

Device Name: Polaris "Dial-A-Date" Contact Lens Case

Indications for Use:

Polaris 'Dial-A-Date' is a contact lens case for storage of soft (hydrophilic), rigid gas permeable, and hard contact lenses. Use for storage during chemical disinfection only.

Not for use during heat disinfection.

Prescription Use ___ _ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

MARC ROBBOY
(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number K120904