FEB 21 2014

Viopti Ltd.
Traditional 510(k) – K131783
For the Contactspod

510(k) Summary

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92.

Submitter's Name:

Viopti Ltd

Submitter's Address:

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Vale of Leven Industrial Estate
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UK

Telephone +44 (0) 1389 714021

Establishment Registration Number:

Still to be established

Contact Person:

Edwin Lindsay

Telephone +44 (0) 7917134922

Date Prepared:

13th January 2014

Viopti Ltd.
Traditional 510(k) – K131783
For the Contactspod

Device Classification Information:

Regulation Number	Device	Device Class	Product Code	Classification Panel
886.5928	Case, contact lens	Class 2	LRX	Ophthalmic

Device Trade Name:

Polaroid Contactspod (and other non-Polaroid branded versions)

Device Common Name:

Contactspod

Intended/ Indications Use:

The Contactspod is a sterile single-use temporary storage case and contains multi-purpose contact lens solution for use with soft contact lenses

It is not a replacement for your normal contact lens rub and rinse cleaning and disinfecting care regime.

It is a clear solution and should not be used, if cloudy or discoloured.

Use for storage during chemical disinfection only. DO NOT USE WITH HEAT.

Summary of Substantial Equivalence:

The Viopti Device is substantially equivalent to WatchDog Group LC - Flip N Slide Contact Lens Case (K130753).

The predicate device table has been prepared to compare the Contactspod with other medical devices already on the market

Property	New Device: Contactspod	Predicate 1
Device Manufacturer	Viopti Ltd	WatchDog Group LC
Device Trade Name	Contactspod	Flip N Slide Contact Lens Case
510(K) Number	K131783 (Pending)	K130753

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Property	New Device: Contactspod	Predicate 1
Device Common Name	Polaroid Contactspod	Flip N Slide Contact Lens Case
Device Product Code	LRX	LRX
Device Classification FDA	Class II	Class II
Intended/ Indications Use	The Contactspod is a sterile single-use temporary storage case and contains multi-purpose solution for use with soft contact lenses.	Intended for the storage of soft (hydrophilic), rigid gas permeable (RGP), or hard contact lenses during chemical disinfection. For use in storage during chemical disinfection only. Do not use during heat disinfection.
Storage case material	Medical grade Polypropylene	Medical grade Polypropylene
Peel off lid material	Aluminium / PE heatseal laminate	Screw Tops Caps
Fluid used for storage of contact lenses	Multi-Purpose Solution- a buffered aqueous solution containing disinfectants / preservatives, buffers, a surfactant, a chelating agent, other ancillary agents and purified water.	Not Supplied with Contact Lens Case
Preservative used	Polyhexamethylene Biguanide (0.0001%)	Not Supplied with Contact Lens Case
Volume of liquid for storage of each lens.	2.5ml	Not Supplied with Contact Lens Case
Method of Sterilization	Gamma Irradiation	Non Sterile
SAL level	10-6 or better	Non Sterile
Intended storage of lenses	Up to 24 hours (temporary storage)	Not Specified

Viopti Ltd.
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For the Contactspod

Property	New Device: Contactspod	Predicate 1
Intended number of uses	Single use	Re-usable Replace case at least every month
OTC or Prescription Device	OTC	OTC
Device Description	The Contactspod is a sterile single use temporary storage case and contains multi-purpose contact lens solution for use with soft contact lenses. The Contactspod comprises an injection moulded medical grade polypropylene case and medical grade TPE basket seal. The contactspod is pre filled with 5ml of multi-purpose solution. The MPS solution is supplied inside the moulded PP case with an aluminium / PE heatseal which is removed by the user. Once lenses are inserted into the solution a secondary seal is used to seal the case.	The contact lens cases are designed for storage of contact lenses. The Colour Contact Lens Case has 2 adjoining wells that have screw top caps. The Flip N Slide contact lens case model has 2 adjoining wells with integral hinged, self –sealing caps in which contact lenses are immersed. The devices are not sterile and are not sterile and are not for heat disinfection. They are made of polypropylene plastic. The volume capacity is 5.91ml on each well of both les cases

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For the Contactspod

Device Description:

The Polaroid Contactspod is a single use, pre-filled contact lens storage case. The product comprises four components:

- A polypropylene storage case, an aluminium foil seal, two TPE baskets and contact lens solution.

The hinged polypropylene case contains the multipurpose contact lens solution stored under an aluminium foil primary seal. Inside the foil seal are two compartments (one for left lens storage and one for right lens storage).

Each compartment has a min 2.4ml of contact lens solution and a TPE basket. The TPE basket has two purposes. The first is to safely hold the lens in the soft TPE material. The second is to provide the secondary seal when the lid is hinged closed and locked with the latch.

The Polaroid Contactspod are sold both as an individual unit and also packaged in conjunction with other eye care and travel products.

Technological Characteristics:

A comparative review of the Contactspod with the predicate devices found that the materials/solution used in the Viopti Contactspod for the temporary storage of Contact Lenses have similar principles of operation and technological characteristics as the previously cleared predicates and thus do not raise any new questions with regards to safety or efficacy.

Performance/Physical Data:

The Contactspod was tested to ensure performance of the system, to verify and validate the product design and to characterize the performance and safety of the Contactspod.

The table outlines the features of the system that were evaluated through testing completed by Viopti.

Test Name	Test Description
Stand Alone Report	The aim of this study was to investigate the sterility and possible antimicrobial activity in a shelf life study of six different lots of the Contactspods prefilled with Multifunctional Solution and radiated by gamma sterilization. The products were tested in the lab using established tests and also by challenging with a standard inoculum of a representative range of microorganisms according to EN-ISO 14729:2001.
Design Verification Testing	The aim of this was to carry out various tests on the Contactspod to verify and validate the product design and to characterize the performance of the Contactspod This included hinge flexing tests, negative air pressure tests to simulate aircraft cabin pressure on both the primary foil seal and the secondary TPE seal, use of product at extremes of indicated temperature, latch opening force both with the foil removed (correct operation) and with the foil in place (misuse), crush force testing of secondary seal, crush force puncture resistance testing with the foil in place, temporary storage of contactspod at extremely high and low temperature.
Microbial load comparison between contact lens cases	Study of the effectiveness of various contact lens cases and concluded that the Contactspod would be an effective one use storage environment for contact lenses.
Review of ISO 14534 – Ophthalmic Optics- Contact lenses and contact lens care products	A review of ISO 14534 – Ophthalmic Optics- Contact lenses and contact lens care products – Fundamental requirements was performed with regards to the Contactspod to ensure compliance. All aspects of the standards were addressed/ reviewed and Contactspod is deemed to be compliant, with the sections applicable to the Contactspod.

Test Name	Test Description
Usability - ISO 62366: 2008/ IEC 62366:2007 – Application of Usability Engineering to Medical Devices	The Contactspod was assessed with regards to usability for compliance with ISO 62366: 2008/ IEC 62366:2007- Medical devices - Application of usability engineering to medical devices

In addition, testing and analysis of the Contactspod has demonstrated compliance to ISO 10993-1: Biological evaluation of medical devices – Guidance on selection of tests and Design Verification Testing was performed to verify the Contactspod.

Safety and Effectiveness:

The Contactspod utilises similar technology currently found in legally marketed predicate devices. Based on testing and comparison with the predicate devices, the Contactspod indicated no adverse indications or results. It is our determination that the Contactspod is safe, effective and performs within its design specifications and is substantially equivalent to the 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 20993-0002

February 21, 2014

Viopti Ltd.
% Mr. Edwin Lindsay, Quality & Regulatory Consultant
Polaroid Building
Vale of Leven Industrial Estate
Dumberton
G82 3PW
United Kingdom

Re: K131783
Trade/Device Name: Contactspod
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LRX
Dated: December 30, 2013
Received: January 8, 2014

Dear Mr. Lindsay:

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 contact 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. 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 -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K131783

Device Name
Contactspod

Indications for Use *(Describe)*

The Contactspod is a sterile single-use temporary storage case and contains multipurpose contact lens solution for use with soft contact lenses. It is not a replacement for your normal contact lens rub and rinse cleaning and disinfecting care regimen. It is a clear solution and should not be used if cloudy or discolored. Use for storage during chemical disinfection only. DO NOT USE WITH HEAT.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joseph C. Hutter -S
2014.02.11 14:19:07 -05'00'

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