

OCT 1 1999



Purilens, Inc.

12170 Race Track Rd.
Tampa, FL 33626

K991965
510(k) Summary

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SUBMITTER:

Submitted on behalf of:

Company Name:	Purilens, Inc..
Address:	12170 Race Track Road Tampa, Florida 33626
Phone:	(813) 814 4141
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CONTACT PERSON: Richard E. Lippman, O.D., F.A.A.O.
Official Representative and Correspondent
C.L. McIntosh & Associates, Inc.
12300 Twinbrook Parkway Suite 625
Rockville, MD 20852

DATE SUMMARY PREPARED: August 26, 1999

TRADE NAME: Purilens^R System
COMMON NAME: contact lens cleaning and disinfection device

DESCRIPTION of the DEVICE:

The device is a cleaning and disinfection unit for contact lenses. It consists of the Purilens Unit and Purilens Solution. The Purilens Unit is compact, with an upper housing containing a germicidal UV light, and a lower housing which contains a removable, clear cleaning chamber with a lens holder for the contact lenses. A mechanism in the lower portion of the cleaning chamber creates the cleaning turbulence activity. Within the lower housing unit is an electronic control unit which operates the UV light and turbulence vibrating mechanism. The lower unit contains an internal automatic timing device which shuts the unit after its 15 minute cycle.

The lens holder consists of a removable basket which houses the contact lenses in separate chambers and is suspended within the cleaning chamber in the lower housing. The removable basket assembly is shielded from the UV light. The cleaning chamber contains an unpreserved saline medium as a storage solution for the contact lenses.

The Purilens Solution is a preservative free saline solution which is used to fill the cleaning chamber. The turbulence mechanism is a magnetic pedal suspended on the end of a flexible spring located in the bottom of the cleaning chamber. When activated by the electronic connection, the pedal oscillates in a subsonic range of 50 - 120 cycles per second creating a whirlpool effect that swirls the Purilens Solution surrounding the lens baskets and removes debris and microorganisms from the lenses during the 15 minute cycle.

UV radiation energy from the upper housing disinfects loosened microorganisms in the solution. Disinfection is accomplished without heating, preservatives, or chemicals. The unit cannot function unless the electrical interlock is complete between the upper and lower housings.

An electrical transformer is located on the power cord. The transformer converts house current of 110 VAC to 14 VAC for the purpose of operating the device.

INDICATIONS FOR USE:

The Purilens^R System is indicated for the cleaning and disinfection of soft (hydrophilic) contact lenses by means of subsonic agitation to remove lens deposits and microorganisms, and ultraviolet irradiation of the surrounding storage solution for disinfection. The lenses may be stored in the disinfected solution for a period of 24 hours following the cleaning and disinfection cycle.

SUBSTANTIAL EQUIVALENCE:

The Purilens^R System for Cleaning and Disinfecting Contact Lenses is substantially equivalent to multipurpose contact lens solution accessory products (ReNu Multipurpose Solution P860023/S6, approved January 24, 1994; and similarly approved multipurpose products) which include ingredients for cleaning and disinfecting contact lenses.

The Purilens^R System is comprised of a two step system. The cleaning step is accomplished by subsonic turbulence created by an agitator wand which is activated by a magnet in close proximity to the wand. This physical agitation of lens solution which aids in removal of lens deposits and microorganisms is substantially equivalent to contact lens ultrasonic cleaners and hand-driven mechanical agitation units (The Lens Comfort, Inc. Ultrasonic Contact Lens Care Accessory, K962112, cleared November 29, 1996; the Sola/Barnes -Hind Soft Mate Automatic Cleaning Unit, K852386, cleared 9/4/85; and the Clensatron 700CL, K884414 cleared 12/29/88). The turbulence created by this action loosens lens deposits and microorganisms from the lens surfaces and places those deposits and microorganisms into the surrounding storage solution, a non-preserved sterile saline. The disinfection step is

accomplished by action of ultraviolet irradiation. This activity is created by the presence of an ultraviolet light source in the device's upper housing. As the UV irradiation energy is emitted, it acts on the loosened microorganisms to reduce the organisms viability.

This device is substantially equivalent to ReNu Multipurpose Solution by Bausch & Lomb, approved under Premarket Approval P860023/S1 on July 28, 1988, and other multipurpose soft contact lens solutions with similar indications. ReNu Multipurpose Solution includes in its formulation, ingredients which clean contact lenses with the aid of digital rubbing, and other ingredients which serve as disinfecting agents when lenses are stored for a minimum of four hours or longer.

The equivalence determination is made by the comparison of actions of the relative devices within their indicated uses. The principal difference between the Purilens^R System and ReNu Multipurpose Solution for cleaning is the cleaning step for the Purilens^R System does not require digital rubbing, but acts by shear forces from subsonic action of the saline solution surrounding the lenses, created by a vibrating agitator. The agitator wand vibrates with sufficient intensity to remove deposits and microorganisms. The cleaning action is equivalent to a series of mechanical cleaning products including The Lens Comfort Contact Lens Care Accessory; the Sola/Barnes-Hind Soft Mate Automatic Cleaning Unit, and the Clensatron, all of which clean lenses by mechanical agitation, either by ultrasonic wave form action of the storage solution, or by mechanical agitation of storage solution in a saline held chamber.

The rinse process for the devices are similar in that the Purilens^R System rinse is accomplished by the continued agitation of the solution during the complete cycle process of the device. This action acts as a continued rinse as the lens is continually "washed" by the action of the subsonic vibration of the storage medium (saline). The equivalent action of rinsing "washing" lenses occurs with the comparable products using mechanical action including the aforementioned devices. This rinse step is further enhanced by a steady stream of saline rinse prior to setting the lenses in the unit to complete the agitation process.

The disinfection step for the Purilens^R System is accomplished by ultraviolet irradiation from the UV bulb housed in the upper housing of the device. The energy emitted by the UV bulb acts on the loosened microorganisms as they are circulating about in the saline storage solution in the carrying case chamber due to continued vibrating subsonic action on the solution medium. The effectiveness of disinfection is complete after 15 minutes in that no microorganisms are recovered after the disinfection cycle is complete on the lenses or in the chamber for up to 24 hours after the cycle is completed. The disinfection step for ReNu Multipurpose Solution is a minimum four hour soak after the lenses are stored in a carrying case with the solution added as a storage medium.

COMPATIBILITY OF THE DEVICE:

A series of pre-clinical studies were performed on the Purilens^R System device in which toxicology studies were performed on the plastic components of the device and determined to be non-toxic and safe for use with contact lenses. The tests conducted included an evaluation of toxicity of residual solution after cycling; a toxicity evaluation by the MEM Elution Method; systemic toxicity in mice; ocular irritation study of extracts in rabbits. A cytotoxicity study was also conducted on the plastic coated agitator found at the base of the portable lens carrier. Solution compatibility studies were performed after 180 cycles of the device on Groups I, II, III, and IV soft contact lenses to determine the stability of lens parameters after cycling and found to have no negative affect on the lens stability or compatibility with the storage solution. Microbiological studies were performed on the lenses, storage solution and lens case to determine whether the device performed the disinfection phase of the cycle, and were determined to have performed all tests successfully. Specific tests which were performed included: disinfection efficacy or "D" value test; multi-item challenge test; evaluation of pH and temperature of the Purilens System chamber solution after cycle completion; and an evaluation of microbial accumulation within the unit (biofilm study).

A lens cleaning analysis using computer image processing quantification of visible light reflections of hydrogel contact lens deposits was performed on all lenses worn in the clinical study. The study documented that the lenses were successfully cleaned and free of deposits including proteins, lipids, and mucins.

CLINICAL ANALYSIS

A clinical study was performed with the device and a control with a comparable multipurpose contact lens cleaning and disinfection system. A crossover design study was employed in which all subjects experienced both the Purilens^R System and the multipurpose disinfection control for three months each. The results of the clinical study indicate that the Purilens^R System performs equally as well as a multipurpose contact lens solution for the same indication. The effect of the use of the Purilens^R System indicates that the performance is superior to a comparable multipurpose cleaning and disinfection system.



OCT 1 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Purilens, Inc.
c/o Richard E. Lippman, O.D., F.A.A.O.
C.L. McIntosh & Associates, Inc.
12300 Twinbrook Parkway, Suite 625
Rockville, MD 20852

Re: K991965

Trade Name: Purilens^R System (consisting of the Purilens Unit and Purilens Solution, a preservative free saline)

Regulatory Class: II
Product Codes: LYL and LPN
Dated: August 26, 1999
Received: August 27, 1999

Dear Dr. Lippman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 – Richard E. Lippman, O.D.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "A. Ralph Rosenthal".

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statement

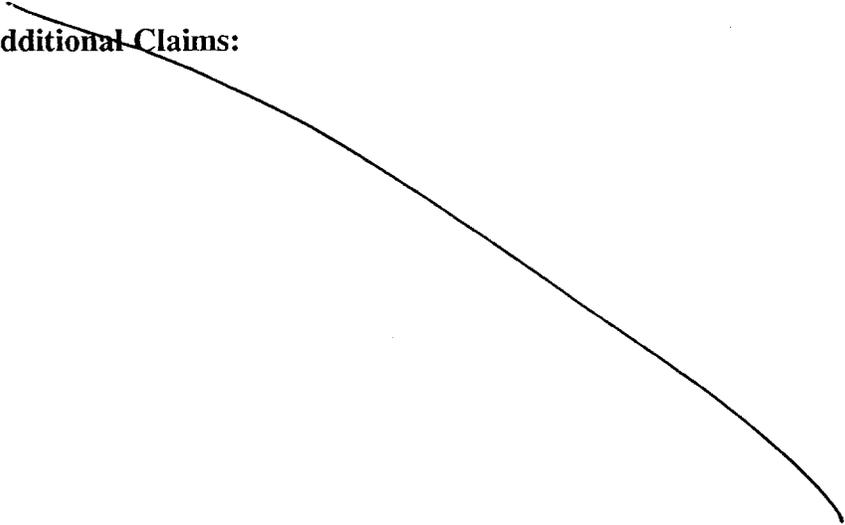
510(k) Number (if known) K991965

Device Name: Purilens^R System

Indications for Use: (Revised: 8/26/99)

The Purilens^R System is indicated for the cleaning and disinfection of soft (hydrophilic) contact lenses by means of subsonic agitation to remove lens deposits and microorganisms, and ultraviolet irradiation of the surrounding storage solution for disinfection. The lenses may be stored in the disinfected solution for a period of 24 hours following the cleaning and disinfection cycle.

Additional Claims:



[Handwritten Signature]

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____

OR

Over -The-Counter Use _____

(Optional Format 1-2-96)

Karen Warburton
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K 991965