JAN 1 3 1999

K982115

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is K982115
Filed on 12 June, 1998

Submitted by:	Daniel Hsu, Ph.D.
Address:	Rim-Wide Companies, Inc. P.O. Box 910184 San Diego, CA 92191-0184
Telephone:	619-622-9956
Facsimile:	619-622-9953
Contact person:	Daniel Hsu, Ph.D.

Identification of the device

Device name:	LENSERVER Automatic
Proprietary/Trade name:	LENSERVER Automatic Contact Lens Cleaning Accessory
Common name:	Contact Lens Cleaning Accessory
Device classification:	Unclassified

Identification of predicate devices

1. Predicate device name: Sola/Barnes-Hind Hydra-Mat
   Manufacturer: Barnes-Hind, Inc.
   510(k) number/clearance information: P810017, P840066

2. Predicate device name: Sola/Barnes-Hind Soft Mate
   Manufacturer: Barnes-Hind, Inc.
   510(k) number/clearance information: K852386
   Predicate device labeling: SOFT MATE Automatic Contact Lens Cleaning Unit

3. Predicate device name: Clensatron 700 CL
   Manufacturer: Questech International, Inc.
   510(k) number/clearance information: K884414
   Predicate device labeling: CLENSATRON Automatic Contact Lens Cleaner

4. Predicate device name: Visonic Dome
   Manufacturer: Vista Vision, Inc.
   510(k) number/clearance information: K902306
   Predicate device labeling: VISONIC DOME Contact Lens Cleaning Accessory

5. Predicate device name: Lensonic

Manufacturer:	Personal Professional Products, Inc.
510(k) number/clearance information:	K921615
Predicate device labeling:	Lensonic Contact Lens Care Accessory

6. Predicate device name: Lens Comfort
   Manufacturer: Lens Comfort, Inc.
   510(k) number/clearance information: K921615
   Predicate device labeling: Lens Comfort Ultrasonic Contact Lens Care Accessory

7. Predicate device name: New Comfort
   Manufacturer: Lens Comfort, Inc.
   510(k) number/clearance information: K974724
   Predicate device labeling: New Comfort Contact Lens Care Accessory

Description of device and reason for submission

The LENSERVER Automatic Contact Lens Cleaning Accessory is an electro-mechanical contact lens cleaning device designed to be used in conjunction with approved contact lens cleaning solutions. The cleaning components of the LENSERVER Automatic consist of a motorized cleaning unit and a partitioned fluid reservoir functioning as the cleaning beaker.

The motorized unit is manufactured from a polymer and houses the battery compartment, motor and control circuits. The fluid reservoir or lens receptacle/cleaning beaker is partitioned and injection molded from medical grade polymer. Fill marks are engraved on the outer wall of the beaker indicating a fluid volume sufficient to completely submerge contact lenses. Each contact lens would be placed into the appropriate compartment, designated 'L' or 'R'.

The base of the fluid reservoir or cleaning beaker fits snugly onto a vibrating platform on the motorized cleaning unit. When placed on the vibrating platform and the power button is actuated, the cleaning beaker vibrates, and after a predetermined period the timing mechanism halts rotation of the motor.

This Premarket Notification is submitted prior to our intent of introducing this device in the United States for the purposes of cleaning contact lenses in conjunction with approved contact lens cleaning solutions.

Intended use

The LENSERVER Automatic Contact Lens Cleaning Accessory is intended for use as an adjunct in cleaning both soft hydrophilic and rigid gas permeable contact lenses using approved contact lens cleaning solutions.

Demonstration of substantial equivalence

The LENSERVER Automatic is preceded by seven approved devices for contact lens cleaning as listed under 'Identification of predicate devices' for use in conjunction with approved solutions. The LENSERVER Automatic is also indicated for use as an accessory for cleaning contact lenses with approved lens solutions. Three of these devices use mechanical or electro-mechanical means of generating hydrodynamic

turbulence that assist in cleaning and the other four listed predicate devices effect cleaning by piezoelectric-induced cavitation. Lens cleaning in the LENSERVER Automatic is also assisted by electro-mechanical agitation of the lenses in cleaning solutions.

Predicate devices contain a fluid reservoir in which lenses and a defined volume of lens solution are placed during cleaning cycles. The LENSERVER Automatic also uses a reservoir in which lenses and defined volumes of solution are in contact during the cleaning cycles. During cleaning in all predicate devices, lenses are individually identified by physical separation and labeling. In the LENSERVER Automatic, lenses are also physically separated in appropriately, and easily identifiable compartments during cleaning cycles.

Physical contact with lenses in all predicate devices occur with medical grade polymers and physical contact with lenses in the LENSERVER Automatic are also with medical grade polymers. These polymers are also used in the predicate devices, or are similar in chemical composition to previously used polymers.

Predicate devices have timing circuits that terminate cleaning after pre-determined periods. The LENSERVER Automatic also has a pre-determined cleaning period.

During lens cleaning the LENSERVER Automatic vibrates by electro-mechanical means. Predicate devices are also electro-mechanical in operation. Other predicate devices use ultrasonic cavitation in assisted cleaning.

The fluid reservoir in LENSERVER Automatic is manufactured by injection molding from medical grade polymer. Fluid reservoirs in predicate devices are manufactured from medical grade polymer or stainless steel.

Pre-Clinical Testing of the LENSERVER Automatic Contact Lens Cleaning Accessory

In vivo Testing

An acute ocular irritation test of solutions from the LENSERVER Automatic was also performed by an independent testing facility, with the conclusion that materials used in the device were safe, as recommended by the Center for Devices and Radiological Health for contact lens care devices.

Compatibility of the LENSERVER Automatic with soft hydrophilic and rigid gas permeable contact lenses in its intended application

The design and indicated use of the LENSERVER Automatic has been determined to be safe and compatible with soft hydrophilic and rigid gas permeable contact lenses. No detectable damage or changes were demonstrated in test lenses following the evaluation program by an independent testing facility.

Device evaluation was performed by highly trained and expert investigators at a recognized college of optometry using a modified protocol obtained from the Division of Ophthalmic Devices at the Office of Device Evaluation. Lens parameters of each new lens were measured prior to and after the series of cleaning cycles. Ten lenses of each

lens type were cycled in ten different LENSERVER Automatic devices for a total of 30 cleaning cycles for each individual lens. The lenses used were two types of soft hydrophilic lenses, FDA groups I and IV, and two different rigid gas permeable lenses of different manufacture.

Clinical testing for this device is not suggested, and was not performed.

The preceding tests conclude that the LENSERVER Automatic is safe when used on contact lenses, and the materials used in construction of this device meet the standards suggested by the FDA for biocompatibility. The LENSERVER Automatic also references the same lens solutions as predicate devices. The LENSERVER Automatic may thus be concluded to be substantially equivalent to predicate devices.

In conclusion, the LENSERVER Automatic Contact Lens Cleaning Accessory is mechanically similar to predicate devices, and like predicate devices, is indicated for use with approved contact lens care solutions, and references the same solutions. Just as predicate devices this device is manufactured with identical or chemically similar medical grade polymers where contact with lenses and solutions occur. Like predicate devices, the LENSERVER Automatic has also been independently demonstrated to be safe and compatible with contact lenses. These data provide justification for the LENSERVER Automatic to be substantially equivalent to predicate devices.

Differences between the LENSERVER Automatic and predicate devices:
During lens cleaning the LENSERVER Automatic vibrates by electro-mechanical means at approximately 900 Hz, while the Clensatron 700 CL rotates at approximately 300 Hz by electro-mechanical means and the Hydra-Mat rotates at approximately 1-10 Hz by manual agitation. The Visonic Dome, Lensonic and Lens Comfort devices generate ultrasonic vibrations at approximately 40,000 Hz to 60,000 Hz.

The LENSERVER Automatic is solely powered by batteries. Predicate devices use UL approved transformers plugged into 110 V AC wall sockets for power, or a combination of transformers and batteries for power.

The fluid reservoir in LENSERVER Automatic is manufactured by injection molding from medical grade polymethylpentene. Fluid reservoirs in predicate devices Lens Comfort and Visonic Dome are manufactured from medical grade stainless steel, while Clensatron and Lensonic use injection molded, medical grade polycarbonate.

<u>In vivo and in vitro tests</u>
Acute ocular irritation test of the LENSERVER Automatic:
Since acute ocular irritation test results of the medical grade polymers used in construction of the LENSERVER Automatic were not available on Material Safety Data Sheets or manufacturers, this test was performed according to guidelines listed in USP XXII using saline cycled through the device in a manner similar to the following test for evaluation of device compatibility with contact lenses. The solution recovered from the LENSERVER Automatic was labeled 'LENSERVER test solution' and unprocessed solution 'Control solution'. These solutions were shipped on ice to a testing facility where the acute ocular irritation tests were performed. The acute ocular irritation test resulted in a conclusion favorable for the LENSERVER Automatic (test results on pages 4.2-4.4).

Compatibility of the LENSERVER Automatic with soft hydrophilic and rigid gas permeable contact lenses in its intended application:
The design and indicated use of the LENSERVER Automatic has been determined to be safe and compatible with soft hydrophilic and rigid gas permeable contact lenses. No detectable damage or changes were demonstrated in test lenses following the evaluation program by an independent testing facility.

Device evaluation was performed by trained investigators at the Southern California College of Optometry, Fullerton, California, using a modified protocol obtained from the Division of Ophthalmic Devices at the Office of Device Evaluation. The following lens parameters of each new lens were measured prior to and after the series of cleaning cycles: power, base curve, diameter and clarity. Ten lenses of each lens type were cycled in ten different LENSERVER Automatic devices for a total of 30 cleaning cycles for each individual lens. The lenses used were two types of soft hydrophilic lenses, FDA groups I and IV, and two different rigid gas permeable lenses of different manufacture.

A detailed report of the evaluation protocol and results appears in Appendix III.

Clinical testing for this device is not indicated, and is not included with this filing.

Substantially equivalent:
The LENSERVER Automatic Contact Lens Cleaning Accessory is mechanically similar to predicate devices, and like predicate devices, is indicated for use with approved contact lens care solutions, and reference the same solutions. Just as predicate devices this device is manufactured with identical or chemically similar medical grade polymers where contact with lenses and solutions occur. Like predicate devices, the LENSERVER Automatic has also been independently demonstrated to be safe and compatible with the indicated contact lenses. These data strongly favor the LENSERVER Automatic to be substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 1999

Rim - Wide Companies
Daniel K. Hsu, Ph.D.
President
P.O. Box 910184
San Diego, California 92191-0184

Re: K982115
Trade Name: LensServer Automatic Contact Lens Cleaning Accessory
Regulatory Class: (unclassified)
Product Code: LYL
Dated: December 1, 1998
Received: December 7, 1998

Dear Dr. Hsu:

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 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 (Premarket 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.

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

If you desire specific advice for your device 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 device, 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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

510(k) NUMBER (IF KNOWN): K982115

DEVICE NAME: LenServer Automatic Contact Lens Cleaning Accessory

INDICATIONS FOR USE:

The LENSERVER Automatic Contact Lens Cleaning Accessory is intended for use as an adjunct in cleaning both soft hydrophilic and rigid gas permeable contact lenses using approved contact lens cleaning solutions.

Examples of approved cleaning solutions indicated for use with the LENSERVER Automatic for soft hydrophilic lenses are the Allergan Soft Mate Consept-1 Cleaning and Disinfecting Solution, Allergan Soft Mate Consept-2 Neutralizing and Rinsing Solution, or Spray. The LENSERVER Automatic is indicated for cleaning rigid gas permeable lenses in conjunction with approved solutions such as Allergan Gas Permeable Daily Cleaner and Allergan ComfortCare Gas Permeable Wetting and Soaking Solution.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel W.C. Brown, Ph.D.

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K982115

Prescription Use ____ OR ~~Over-The-Counter-Use~~ ✓
(Per 21 CFR 801.109) (Optional Format 1-2-96)