K 974724

510(k) SUMMARY
(807.92(c))

[807.92(a)(1)]
Prepared: December 8, 1997

Reference: 510(k) Summary

MAR - 2 1998

Submission by: James Demestichas

Entity: Lens Comfort, Inc.
912 Broad Street
Elizabeth, New Jersey 07280
973-633-6726
973-633-7231 Fax

[807.92(a)(2)]
Classification Name and Code: Not Classified
Accessory to Contact Lens Solutions
Product Code (86LYL)

Common or Usual Name: Ultrasonic Contact Lens Care Accessory

Trade or Proprietary Name: New Comfort Contact Lens Care Accessory

[807.92(a)(3)]
Equivalence: The Sola/Barnes-Hind® Hydra-Mat® (PMA Nos. P 810017 and P 840066); the Sola/Barnes-Hind® Soft Mate® Automatic Cleaning Unit (K 852386); the Clensatron® 700 CL (K 884414); the Visonic Dome™ (K 902306); the Lensonic (K 921615); and Lens Comfort Contact Lens Care Accessory (K 962112) all have been given market clearance to be used as an accessory for contact lens care.

[807.92(a)(4)]
Device Description: The New Comfort Ultrasonic Contact Lens Care Accessory uses a piezo-electric crystal to generate a wave form, in a reservoir containing a specific volume of fluid. Cavitation in fluid results in the generation of microscopic bubbles that implode upon the lens surface. The matrix of frequency, duration of ultrasound, and the control of temperature rise in the fluid medium leads to cleaning when a specific contact lens solution is present. The New Comfort device uses standard power (110 v/120 v). There is a four (4) foot cord and a UL approved wall transformer.

The New Comfort device consists of the housing, lens baskets, a reservoir, electronics and a transducer. All components that come in contact with contact lenses or solutions are of medical grade composition and have been used in legally marketed predicate devices in the United States. The housing is injection molded of ABS. The baskets and supporting structure are injection molded from ABS. The reservoir is deep drawn stainless steel, is passivated and electropolished. The electronic circuitry has been used in other cleaning applications in other industries for years. The single crystal is affixed directly to the bottom of the reservoir with an epoxy generally used in cleaning applications in the ultrasound industry.

[807.92(a)(5)]
Intended Use: The New Comfort Contact Lens Care Accessory is intended for use in conjunction with contact lens solutions as an accessory in the cleaning of contact lenses.

The New Comfort Contact Lens Care Accessory is indicated as aid for cleaning as an accessory for soft hydrophilic lenses and gas permeable lenses when used with the appropriate Allergan® Soft Mate® solutions such as the Consept® Cleaning and Disinfection System which is comprised of the Allergan® Soft Mate® Consept®-1 Cleaning and Disinfecting solution and Allergan® Soft Mate® Consept®-2 Neutralizing and Rinsing Solution or Spray. The New Comfort Contact Lens Care Accessory is indicated for use for gas permeable solutions such as Allergan® Gas Permeable Daily Cleaner and Allergan® ComfortCare GP Wetting and Soaking Solution. The New Comfort Contact Lens Care Accessory may be used for a receptacle for chemical disinfection.

[807.92(a)(6)]
Comparison of Technological Characteristics: The predicate devices are:

1.	Sola/Barnes-Hind® Hydra-Mat®	P 810017 P 840066
2.	Sola/Barnes-Hind® Soft Mate® Automatic Cleaning Unit	K 852386
3.	Clensatron® 700 CL	K 884414
4.	Visonic Dome™	K 902306
5.	Lensonic	K 921615
6.	Lens Comfort	K 962112

Similarities:

All predicate devices have referenced Sola/Barnes-Hind® Solutions (now Allergan) in their submissions and specifically the Soft Mate® Concept®-1 and 2 Cleaning and Disinfection System for use with soft lenses. Lens Comfort and New Comfort

references the same solutions and data.

The predicate devices use medical grade materials that are in contact with the contact lenses or the solutions and have been previously used in ophthalmic medical devices legally marketed in the United States. Materials in New Comfort are the same or similar as predicate devices.

All predicate devices have a fluid reservoir in which lenses are submerged. The New Comfort device has a similar reservoir and submerges lenses for cleaning.

All predicate devices have plastic lens baskets into which lenses are encased for submersion while cleaning is in process. New Comfort has plastic lens baskets.

All predicate devices operate on standard power from a wall receptacle. New Comfort has a cord with a UL approved transformer that plugs into a wall socket.

Three predicate devices Lensonic, Visonic Dome™ and Lens Comfort use piezo-electric crystals in the generation of cavitation as does New Comfort.

Differences:

New Comfort operates at a frequency of approximately 100 Khz and yields approximately 100,000 vibrations per second. The Hydra-Mat® is hand operated. The SoftMate® Automatic Cleaning Unit vibrates a small fraction of that of any of the predicate devices. The Clensatron® 700CL is belt driven and yields 300 cycles a minute. The Visonic Dome™ is ultrasonic and generates approximately 40,000 vibrations a second. The Lensonic device is ultrasonic and generates approximately 60,000 vibrations per second. The Lens Comfort device operates at a frequency of approximately 65 Khz.

New Comfort operates in a specific and controlled range of end temperatures. The predicate devices have end temperatures running from ambient to above 55° C. The New Comfort device end temperature is in the middle temperature range of the predicate devices.

New Comfort uses .5 to 1 watts of power per milliliter of fluid and the predicate devices range from 1 watt to 8 watts

New Comfort, Lens Comfort, Clensatron® and Lensonic® all have wall transformers while the Visonic Dome™ has no cord and plugs directly into an electrical outlet.

New Comfort, Lens Comfort, Lensonic® and Clensatron® all have a start button. New Comfort, Lens Comfort and Lensonic® have an (LED) that glows and then automatically shuts off after the end of the 10 minute cycle. The Hydra-Mat® has no time indicators. The Soft Mate® Automatic Cleaning unit has a timer but it

correlates to the vibration cycle and there is no light indicator. The Clensatron® has a timer to stop the revolutions of the basket in the reservoir, but it has no light/time indicator to define for the user the end of a cycle. The Visonic Dome™ has a light that shuts off when the ultrasound stops, which coincides with the end of a 10 minute cycle. Lensonic has a light that shuts off at the end of 10 minutes.

To create cavitation, the Visonic Dome™ uses a piezo-electric crystal, affixed to the bottom of the stainless steel reservoir. Lensonic uses two piezo-electric crystals combined with a multi-part transducer affixed to a polycarbonate tank. New Comfort and Lens Comfort uses a piezo-electric crystal affixed to the bottom of a stainless steel reservoir.

The Visonic Dome™ runs ultrasound for 10 minutes. Lensonic® runs ultrasound for 3 plus minutes. New Comfort and Lens Comfort runs ultrasound for approximately 3 minutes.

[807.92(b)(1)]

Evaluation of the New Comfort, based on a protocol used by the industry to assess the effectiveness of systems and solutions designed to clean contact lenses, was conducted by an optometrist who is director of optometric services in a large ophthalmology practice.

A protocol was obtained from the Office of Device Evaluation (ODE) that has been used by the industry to assess the effectiveness of devices and cleaning solutions and their impact, if any, on the contact lenses. Lenses were selected from Group 1, Group 3, Group 4 and the Gas Permeable class. They were soaked in an artificial tear solution. Physical and optical parameters were measured before the lenses were treated with the artificial tear solution and then after each cycle. Thirty (30) cycles were performed on all lenses.

No changes were noted in color, clarity, power, diameter or base curve. The lenses all appeared clear and no deposits or residue or damage were noted on any of the lenses.

The Company did not have access to comparative data from the predicate devices other than Lens Comfort, but believe that the test results recorded by the investigator were sufficient to support the premise that the Company's device performs to the standards intended by the protocol.

[807.92(b)(2)]

Clinical data is not needed and has not been submitted with this 510(k).

[807.92(b)(3)]

The data gathered from the cycling tests, strongly supports substantial equivalence between the New Comfort and Lens Comfort Device as well as predicate devices classified as contact lens care accessories (86 LYL). Cycling tests produced no physical or optical parameter changes after 30 cycles. There was no reported deposits or residual film observed on test lenses after the tests were concluded. There was no damage to lenses observed. The New Comfort device referencees the same solutions as all the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 2 1998

Mr. James Demestichas
Regulatory Affairs Officer
Lens Comfort, Inc.
912 North Broad St.
Elizabeth, NJ 07208

Re: K974724
Trade Name: The New Comfort Contact Lens Care Accessory (Ultrasonic Cleaning Accessory)
Regulatory Class: Unclassified
Product Code: LYL
Dated: December 8, 1997
Received: December 18, 1997

Dear Mr. Demestichas:

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 at (301) 443-6597.

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) K 974724

Device Name: Lens Comfort Contact Lens Accessory

Indications For Use:

The New Comfort Contact Lens Care Accessory is intended for use in conjunction with contact lens solutions as an accessory in the cleaning of contact lenses.

The New Comfort Contact lens Care Accessory is indicated as aid for cleaning as an accessory for soft hydrophilic lenses and gas permeable lenses when used with the appropriate Allergan® Soft Mate® solutions such as the Consept® Cleaning and Disinfection System which is comprised of the Allergan® Soft Mate® Consept®-1 Cleaning and Disinfecting solution and Allergan® Soft Mate® Consept®-2 Neutralizing and Rinsing Solution or Spray. The New Comfort Contact Lens Care Accessory is indicated for use for gas permeable solutions such as Allergan® Gas Permeable Daily Cleaner and Allergan® ComfortCare GP Wetting and Soaking Solution. The New Comfort Contact Lens Care Accessory may be used for a receptacle for chemical disinfection.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature], PhD

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number, K 974724

Prescription Use ___ OR Over-The-Counter Use ✓
(per 21 CFR 801.109)

(Optional Format 1-2-96