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510(k) SUMMARY
(807.92(a))

K962112

[807.92(a)(1)]

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[807.92(a)(2)]**Classification**

Name and Code: Not Classified
Accessory to Contact Lens Solutions
Product Code (88LYL)

Common or Usual

Name: Ultrasonic Contact Lens Care Accessory

Trade or**Proprietary**

Name: Lens Comfort Contact Lens Care Accessory

[807.92(a)(3)]

Equivalence: The Solo/Barnes-Hind® Hydra-Mat® (PMA Nos. P 810017 and P 840068); the Solo/Barnes-Hind® Soft Mate® Automatic Cleaning Unit (K 852386); the Cienatron® 700 CL (K 884414); the Visonic Dome™ (K 902306); and the Lensonic (K 921615) all have been given market clearance to be used as an accessory for contact lens care.

[807.92(a)(4)]**Device**

Description: The Lens 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 Lens Comfort device uses standard power (110 v/120 v). There is a four (4) foot cord and a UL approved wall transformer .

The Lens Comfort device consists of the housing, lens baskets, a reservoir,

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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 polycarbonate. The baskets and supporting structure are injection molded from polyethylene. The reservoir is deep drawn stainless steel, is passivated and polished. 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)(8)]

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

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

[807.92(a)(8)]

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 854414
4.	Visionic Dome™	K 902306
5.	Lensonic	K 921615

Similarities:

All predicate devices have referenced Sola/Barnes-Hind® Solutions in their submissions and specifically the Soft Mate® Concept®-1 and 2 Cleaning and Disinfection System for use with soft lenses. Lens Comfort references the same solutions and data.

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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 Lens Comfort are the same or similar as predicate devices.

All predicate devices have a fluid reservoir in which lenses are submerged. The Lens 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. Lens Comfort has plastic lens baskets.

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

Two predicate devices Lensonic and Visonic Dome™ as well as Lens Comfort use piezo-electric crystals in the generation of cavitation.

Differences:

Lens Comfort operates at a frequency of approximately 65 KHz and yields approximately 60,000 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 Cleansatron® 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.

Lens 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 Lens Comfort device end temperature is in the middle temperature range of the predicate devices.

Lens Comfort uses 5 watts of power and the predicate devices range from 1 watt to 8 watts.

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

Lens Comfort, Lensonic® and Cleansatron® all have a start button. 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 Cleansatron® 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

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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 a piezo-electric crystal combined with a multi-part transducer affixed to a polycarbonate tank. 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. Lens Comfort runs ultrasound for approximately 3 minutes.

[807.92(b)(1)]

Evaluation of the Lens Comfort Device, 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, 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 Lens Comfort Device and predicate devices classified as contact lens care accessories. Cycling tests produced no physical or optical parameter changes

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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 Lens Comfort device reference the same solutions as the predicate devices.

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