

OCT 18 1999

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:

K992692

Applicant information:

Date Prepared: August 9, 1999

Name: **Benz Research and Development**
Address: P.O. Box 1839
Sarasota, Fl 34230-1839

Contact Person: Jose A. Ors, Ph.D.
Vice President
Benz Research & Development, Inc.

Phone number: (941) 758-8256

USA Consultant: Med-Vice Consulting, Inc.
Martin Dalsing

Phone number: (970) 243-5490
Fax number: (970) 243-5501

Device Information:

Device Classification: Class II

Classification Number: LPL

Classification Name: Lens, Soft Contact, Daily Wear

Trade Name: **59% extreme H₂O[®] (hioxifilcon A) soft contact lens**

Purpose of 510(k) Submission:

Benz Research and Development is requesting clearance from the FDA to implement the manufacturing process change of "lathe-cut to cast-molded" for the 59% extreme H₂O[®] soft contact lens.

Equivalent Device:

The 59% extreme H₂O[®] "cast-molded" soft contact lens is substantially equivalent to the Benz Research and Development Benz Lens "lathe cut" version.

Device Description:

The 59% extreme H₂O[®] (hioxifilcon A) soft contact lens are hemispherical shells with molded spherical base curves and molded front surfaces. The 59% extreme H₂O[®] soft contact lens are fabricated from (hioxifilcon A) which is a non-ionic, ultra high molecular weight copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2,3-Dihydroxypropyl Methacrylate (Glycerol Methacrylate, GMA). It consists of 41% hioxifilcon A and 59% water by weight when immersed in normal saline solution buffered with either sodium bicarbonate or sodium perborate. The lens is available in clear and with a blue visibility handling tint, phthalocyanato (2) - (copper).

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The physical properties of the lens are:

PROPERTY	VALUE
Refractive Index	1.515 (dry) 1.404 (hydrated)
Light Transmission:	greater than 95%
Water Content	59 %
Specific Gravity	1.308 (dry) 1.136 (hydrated)
Oxygen Permeability (Dk Value)	18 X 10 ⁻¹¹ Fatt Units (cm ² /sec)(ml O ₂ /ml x mm Hg @ 35°C), revised Fatt method

Intended Use:

The 59% extreme H₂O[®] (hioxifilcon A) soft contact lens for daily wear are indicated for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes that are myopic or hyperopic. The lens may be worn by persons who exhibit refractive astigmatism of .75 Diopters or less that does not interfere with visual acuity. The lens are available clear and with a blue visibility handling tint.

Eyecare practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using either a heat or chemical disinfection system.

Substantial Equivalence:

The 59% extreme H₂O[®] (hioxifilcon A) soft contact lens will be manufactured according to specified process controls and an ISO 9001/EN46001 and CGMP quality assurance program currently in place. The established safety profile (physical/chemical/optical and toxicological performance) of the 59% extreme H₂O[®] (hioxifilcon A) soft contact lens "cast-molded" is equivalent to the 59% extreme H₂O[®] (hioxifilcon A) soft contact lens "lathe-cut", the predicate device previously identified. Side by side comparison test results yield that the physical/chemical/optical and toxicological performance characteristics of the cast-molded contact lens are equivalent to the lathe-cut predicate device contact lens.

Being similar with respect to the physical/chemical/optical and toxicological performance characteristics to the predicate device, this meets the requirements per section 510(k) of the act regarding substantial equivalence and does not raise different questions of safety and effectiveness than the predicate device identified above.



OCT 18 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Benz Research and Development Company
C/O Mr. Martin Dalsing
Medvice Consulting, Inc.
623 Glacier Drive
Grand Junction, CO 81503

Re: K992692

Trade Name: 59% extreme H₂O (hioxifilcon A) Soft Contact Lens for Daily Wear
(cast-molded, clear and visibility tint)

Regulatory Class: II

Product Code: 86 LPN

Dated: August 9, 1999

Received: August 11, 1999

Dear Mr. Dalsing:

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 (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 - Mr. Martin Dalsing

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

INDICATIONS FOR USE STATEMENT

Device Name: 59% extreme H₂O[®] (hioxifilcon A) soft contact lens

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David W. J. Brown, Ph.D.

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K992692

Prescription Use X
(Per 21 CFR 801.109)

or

Over-The-Counter Use

(Optional Format 1-2-96)