K101122

BENZ RESEARCH & DEVELOPMENT
510(k) Premarket Notification

AUG - 9 2010

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:

Applicant Information:

Date Prepared:	April 14, 2010
Name:	Benz Research & Development 6447 Parkland Drive Sarasota, FL 34243
Contact Person:	Giovanny Espinosa / Patrick H. Benz, Ph.D. Assoc. Regulatory Affairs / President Benz Research & Development
Phone number:	941-758-8256
Fax number:	941-758-1191

Device Information:

Device Classification:	Class II
Classification number:	LPL
Classification Name:	Lens, Soft Contact, Daily Wear
Trade Name:	Benz-G 4X (Hioxifilcon D) Multifocal Lenses

Purpose of the 510(k) Submission:

Benz Research & Development is requesting clearance from the FDA to manufacture and market Benz-G 4X (Hioxifilcon D) Multifocal Lathed Lenses.

Predicate Devices:

The Benz-G 4X (Hioxifilcon D) Multifocal Lathed soft contact lens is substantially equivalent to the Benz-G 4X (Hioxifilcon D) Lathed Lens already cleared under 510(k) K062854.

Device Description:

The Benz-G 4X (Hioxifilcon D) Multifocal Lathed soft contact lenses are hemispherical shells and are available as multifocal lens designs. The Benz-G 4X (Hioxifilcon D) Multifocal Lathed soft contact lens is fabricated from Hioxifilcon D, which is a non-ionic copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2,3-Dihydroxypropyl Methacrylate (Glycerol Methacrylate, GMA) and cross-linked with ethylene glycol dimethacrylate (EGDMA). It consists of 46% Hioxifilcon D and 54% water by weight when immersed in normal buffered saline solution buffered. The lens is available 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.

Intended Use (Indications):

The Benz-G 4X 54% (Hioxifilcon D) Multifocal Lathed soft contact lens for daily wear is indicated for the correction of visual acuity in aphakic or non-aphakic persons with non-diseased eyes that are myopic, hyperopic, possess astigmatism of 10.0 diopters or less and are presbyopic. The spherical lens may be worn by persons who exhibit astigmatism of 0.75 Diopters or less that does not interfere with visual acuity. The toric lens may be worn by persons who exhibit astigmatism of up to 10.0 Diopters.

Eye care 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 a chemical disinfection system.

Comparison to Predicate Device:

Side by side comparison testing was conducted on the Benz-G 4X (Hioxifilcon D) Lathed Lens already cleared under 510(k) K062854, and Multifocal Lenses manufactured by Benz Research & Development from Hioxifilcon D material.

	Predicate Device	**New Device**
	Benz-G 4X Lathed Lens K062854	**Benz-G 4X Multifocal Lens**
Intended Use:	Intended for daily wear for the correction of visual acuity in aphakic and non-aphakic persons with non-diseased eyes that are myopic or hyperopic. The spherical lens may be worn by persons who exhibit astigmatism of 0.75 Diopters or less that does not interfere with visual acuity. The toric lens may be worn by persons who exhibit astigmatism of up to 10.0 Diopters. Lenses are intended for frequent and/or planned replacement wear as prescribed by the eye care practitioner.	Intended for daily wear for the correction of visual acuity in aphakic and non-aphakic persons with non-diseased eyes that are myopic, hyperopic, possess astigmatism of 10.0 diopters or less and are presbyopic. The spherical lens may be worn by persons who exhibit astigmatism of 0.75 Diopters or less that does not interfere with visual acuity. The toric lens may be worn by persons who exhibit astigmatism of up to 10.0 Diopters. Lenses are intended for frequent and/or planned replacement wear as prescribed by the eye care practitioner.
USAN Name:	Hioxifilcon D	Hioxifilcon D
Classification Number:	LPL	LPL
Classification Name:	Soft (hydrophilic) contact lens, daily wear	Soft (hydrophilic) contact lens, daily wear
Material Classification:	FDA Group 2 (> 50% H_2O, non-ionic polymer)	FDA Group 2 (> 50% H_2O, non-ionic polymer)
Production Method:	Lathe-Cut	Lathe-Cut
Water content:	54% ± 2	54% ± 2
Specific Gravity	1.299 (dry)	1.299 (dry)
Expansion:	1.35	1.35
Refractive Index:	1.408 hydrated	1.408 hydrated
Light Transmission:	Greater than 95% T	Greater than 95% T
Tint	Blue Phthalocyanato (2) – (copper)	Blue Phthalocyanato (2) – (copper)
Oxygen Permeability	18×10^{-11} Fatt Dk units (Fatt method) 23×10^{-11} Fatt Dk units (cm^2/sec)(ml O_2/ml x mm Hg) ANSI Z80:2004 polarographic method corrected for boundary-layer end edge effects	18×10^{-11} Fatt Dk units (Fatt method) 23×10^{-11} Fatt Dk units (cm^2/sec)(ml O_2/ml x mm Hg) ANSI Z80:2004 polarographic method corrected for boundary-layer end edge effects
Shore D Hardness:	89	89

Optical Zone	Optic Zone: 7.971	Optic Zone: 8.0 OZ1: 1.8 – 6.2 OZ2: 6.2 – 1.8
Tensile Properties: **Breaking Force** **Tensile Strength** **Modulus** **Elongation**	 57 gms 25 g/sq.mm 21 g/sq.mm 186%	 57 gms 25 g/sq.mm 21 g/sq.mm 186%

Clinical Data:

It was determined that clinical studies were not necessary to establish the safety and effectiveness of the Benz-G 4X (Hioxifilcon D) Multifocal Lathed lenses.

This Benz-G 4X (Hioxifilcon D) material is identical to the previously cleared Benz-G 4X (Hioxifilcon D) under K062854.

The Benz-G 4X (Hioxifilcon D) Multifocal Lathed lenses have the identical manufacturing process (lathe-cut versus lathed-cut) as the marketed lens Benz-G 4X (Hioxifilcon D) Lathed.

Conclusion:

The information provided in this premarket submission establishes that the Benz-G 4X (Hioxifilcon D) Multifocal Lathed lenses is substantially equivalent in terms of intended use, materials, toxicological and physiochemical properties to the predicate device, Benz-G 4X (Hioxifilcon D) Lathed Lens. This change is to correct the visual acuity in aphakic and non-aphakic persons with non-diseased eyes that are myopic, hyperopic, possess astigmatism of 10.0 diopters or less and are presbyopic. This visual acuity correction is achieved with the addition of another optical zone.

	Predicate Device	**New Device**
	Benz-G 4X Lathed Lens K062854	Benz-G 4X Multifocal Lens
Optical Zone	Optic Zone: 7.971	Optic Zone: 8.0 OZ1: 1.8 – 6.2 OZ2: 6.2 – 1.8

In addition, the Benz-G 4X (Hioxifilcon D) Multifocal Lathed lenses are manufactured at Benz Research & Development according to the identical manufacturing processes as the following previously cleared hydrophilic contact lenses:

Benz-G 4X (Hioxifilcon D) K062854

This Benz-G 4X (Hioxifilcon D) material is identical to the previously cleared Benz-G 4X (Hioxifilcon D) under K062854.

Benz-G 4X (Hioxifilcon D) Multifocal lathed lens therefore meets the requirements of substantial equivalence and is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Benz Research & Development
c/o Mr. Giovanny Espinosa
Associate Regulatory Affairs
6447 Parkland Drive
Sarasota, FL 34243

AUG - 9 2010

Re: K101122
Trade/Device Name: bemz-G 4X (Hioxifilcon D) Multifocal Lathed Contact Lenses
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: June 28, 2010
Received: June 30, 2010

Dear Mr. Espinosa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K101122

Indications for Use

AUG - 9 2010

510(k) Number (if known): K101122

Device Name: Benz-G 4X (Hioxifilcon D) Multifocal Lathed Contact Lenses

Indications For Use: The Benz-G 4X 54% (Hioxifilcon D) Multifocal Lathed soft contact lens for daily wear is indicated for the correction of visual acuity in aphakic or non-aphakic persons with non-diseased eyes that are myopic, hyperopic, possess astigmatism of 10.0 diopters or less and are presbyopic. The spherical lens may be worn by persons who exhibit astigmatism of 0.75 Diopter or less that does not interfere with visual acuity. The toric lens may be worn by persons who exhibit astigmatism of up to 10 Diopters.

Eye care 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 a chemical disinfection system.

Prescription Use ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jennifer M. Brown

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K101122