JUL 23 2008

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: K080512

Applicant information:

Date Prepared:	June 9, 2008
Name:	**Metro Optics of Austin, Inc.**
Address	15802 Vision Drive Pflugerville, TX 78660
Contact Person:	Steve Webb President
Phone number:	(512) 251-2382
Consultant:	Martin Dalsing Medvice Consulting, Inc. 806 Kimball Avenue Grand Junction, CO 81501
Phone number	(970) 243-5490

Device Information:

Device Classification:	Class II
Classification Number:	LPL
Classification Name:	Lenses, Soft Contact, Daily Wear
Trade Name:	**RevitalEyes, Post-Surgical Soft Daily Wear Contact Lens (Hioxifilcon B) clear and blue visibility tint.**

Equivalent Devices:

The **RevitalEyes, Post-Surgical Soft Daily Wear Contact Lens (Hioxifilcon B) clear and blue visibility tint** are substantially equivalent to the following predicate devices in terms of contact lens material, intended use and design.

Predicate devices include:

Metro-G 3X, manufactured by Metro Optics of Austin, K964902

FlexLens Post Refractive Surgery, manufactured by FlexLens, K961943

Device Description:

The **RevitalEyes, Post-Surgical Soft Daily Wear Contact Lens (Hioxifilcon B) clear and blue visibility tint**, which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of these materials allows the lens to become soft and pliable when immersed in an aqueous solution.

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 (hioxifilcon B) soft hydrophilic contact lens has a spherical back 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 hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 49% water by weight. The physical properties of the lens are:

(Hioxifilcon B)

Refractive Index	1.51 (dry) 1.42 (hydrated)
Light Transmission	greater than 94%
Surface Character	hydrophilic
Water Content	49 %
Specific Gravity	1.137 (hydrated)
Oxygen Permeability	16.40 X 10^{-11} (cm^2/sec) (ml O_2/ml x hPa @ 35°C), (revised Fatt method).

Intended Use:

The **RevitalEyes, Post-Surgical Soft Daily Wear Contact Lens (Hioxifilcon B) clear and blue visibility tint** may be prescribed for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in other wise non-diseased eyes that require a soft contact lens for the management of surgically altered corneas following LASIK, PRK or RK surgery.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

Substantial Equivalence:

The device will be manufactured according to specified process controls and a quality assurance program. The established safety profile (pre-clinical toxicology, clinical study data, manufacturing/chemistry data) of the device is equivalent to the BENZ-G 3X. Being similar with respect to indications for use, materials, physical construction and safety & effectiveness to the predicate devices, 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 devices identified above.

The following matrix illustrates the production method, lens function and material characteristics of the **RevitalEyes, Post-Surgical Soft Daily Wear Contact Lens (Hioxifilcon B) clear and blue visibility tint**, as well as the predicate devices.

Substantial Equivalence Matrix

	RevitalEyes New Device	Flexlens Post Refractive Surgery (hefilcon A) predicate device	METRO-G (hioxifilcon B) predicate device
Intended Use	Indicated for daily wear and may be prescribed in other wise non-diseased eyes that require a soft contact lens for the management of surgically altered corneas following LASIK, PRK or RK surgery.	Indicated for daily wear and may be prescribed in other wise non-diseased eyes that require a soft contact lens for the management of surgically altered corneas following refractive surgery.	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.
Functionality	same as predicate device	After machining from the optical blank, the contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.	After machining from the optical blank, the contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.
Indications	same as predicate device	Daily wear, Soft (hydrophilic) contact lens	Daily wear, Soft (hydrophilic) contact lens
Production Method	same as predicate device	Lathe-cut	Lathe-cut
FDA Group #	same as predicate device	Group # 1 < 50% Water, Nonionic Polymers	Group # 1 < 50% Water, Nonionic Polymers
USAN name	Hioxifilcon B	Hefilcon A	Hioxifilcon B
Water Content	48%	45.0%	48.0%
Oxygen Permeability	16.40 X 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).	13.2 X 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).	16.40 X 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).
Specific Gravity	1.137	1.142	1.137

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 2008

Metro Optics of Austin, Inc.
c/o Martin Dalsing
Official Correspondent
Medvice Consulting, Inc.
806 Kimball Avenue
Grand Junction CO 81501

Re: K080512
Trade/Device Name: RevitalEyes Post-Surgical Soft Daily Wear Contact Lens (hioxifilcon B) clear and blue visibility tint
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: June 9, 2008
Received: June 18, 2008

Dear Mr. Dalsing:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

INDICATIONS FOR USE STATEMENT

Device Name: **RevitalEyes, Post-Surgical Soft Daily Wear Contact Lens (Hioxifilcon B) clear and blue visibility tint.**

INDICATIONS FOR USE:

The **RevitalEyes, Post-Surgical** (Hioxifilcon B) Soft Contact Lenses for daily wear may be prescribed in other wise non-diseased eyes that require a soft contact lens for the management of surgically altered corneas following LASIK, PRK or RK surgery.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

(PLEASE DO OT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K080512

Prescription Use X (Per 21 CFR 801.109) or Over-The-Counter Use ___

(Optional Format 1-2-96)