K 011316 JUN 13 2001

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 27, 2001
Name:	**American BioCurve, Inc.**
Address	15970 Bernardo Center Dr. San Diego, CA 92127
Contact Person:	John Kenyon
Phone number:	(800) 959-2020
USA Consultant:	Martin Dalsing Medvice Consulting, Inc. 623 Glacier Drive Grand Junction, CO 81503
Phone number	(970) 243-5490 Fax (970) 243-5501 Email: mdalsing@gj.net

Device Information:

Device Classification:	Class II
Classification Number:	LPL
Classification Name:	Lenses, Soft Contact, Daily Wear
Trade Name:	**BIOCURVE SOFT (hioxifilcon A) Spherical and Toric Soft Contact Lens for Daily Wear (clear and blue visibility-handling tint, lather-cut).**

Purpose of 510(k) submission:

NEW DEVICE ~

American BioCurve, Inc. proposes to manufacture the BIOCURVE SOFT (hioxifilcon A) Spherical and Toric Soft Contact Lens for Daily Wear (clear and blue visibility-handling tint, lathe-cut). Data supporting substantial equivalency to the predicate devices, performance, and safety and efficacy of the (hioxifilcon A) polymer is contained in this submission.

Equivalent Devices:

The **BIOCURVE SOFT (hioxifilcon A) Spherical and Toric Soft Contact Lens for Daily Wear (clear and blue visibility-handling tint, lathe-cut)** is substantially equivalent to the following predicate devices.

- BIOCURVE SOFT (methafilcon A) manufactured by American Contact Lens, Inc. (K001585)
- BENZ-G 5X manufactured by BENZ Research and Development Corp. (K952620)

Device Description:

The **BIOCURVE SOFT (hioxifilcon A) Spherical and Toric Soft Contact Lens for Daily Wear (clear and blue visibility-handling tint, lathe-cut)** is fabricated from hioxifilcon A, which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material 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 A) 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 non-ionic lens material, (hioxifilcon A) is a 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 42% hioxifilcon A and 58% water by weight when immersed in normal saline solution buffered with sodium bicarbonate. The lenses are available in clear and with a blue visibility-handling tint, phthalocyanato (2) – (copper).

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 58% water by weight. The physical properties of the lens are:

Refractive Index	1.404
Light Transmission (clear)	greater than 95% T
Light Transmission (tinted)	greater than 95% T
Water Content	58 %
Specific Gravity	1.308 (dry) 1.136 (hydrated)
Oxygen Permeability	20 X 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C), (revised Fatt method).

Intended Use:

The **BIOCURVE SOFT (hioxifilcon A) Spherical** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of 1.00 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear and with a blue visibility-handling tint.

The **BIOCURVE SOFT (hioxifilcon A) Toric** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10 diopters. The lens is 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 a chemical disinfecting system.

Pre-Clinical Performance Data:

Pre-clinical performance data addressing the cytotoxicity test, systemic injection test, and ocular eye irritation test can be referenced in the 510(k) # K964528.

American Biocurve, Inc. has also included in this 510(k) notification the results of several lenses manufactured utilizing the lathe-cut process to a variety of prescribed specifications to verify the ability of the manufacturer to make manufacture lathe-cut lenses from the hioxifilcon A material.

Substantial Equivalence:

The device will be manufactured according to specified process controls and a quality assurance program already in place. The device will undergo manufacturing, packaging and sterilization procedures similar to devices currently marketed and distributed by American BioCurve, Inc. 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 table illustrates that the production method, lens function and indications for use of the are **BIOCURVE SOFT (hioxifilcon A) Spherical and Toric Soft Contact Lens for Daily Wear (clear and blue visibility-handling tint, lathe-cut)** substantially equivalent to the predicate devices. In addition, the water content, material, polymer, dK value, and light transmission are as well substantially equivalent to the predicate devices.

Substantial Equivalence Table

	Characteristic	BIOCURVE SOFT (hioxifilcon A) (new device)	BIOCURVE SOFT (methafilcon A) (predicate device)	BENZ 5X (predicate device)
1.)	**PRODUCTION METHOD**	Lathe-Cut	Lathe-Cut	Lathe-Cut
2.)	**LENS FUNCTION and DESIGN**	Refractive medium that focuses light rays from distant, intermediate and near objects on the retina, while compensating for refractive error.	Refractive medium that focuses light rays from near, intermediate and distant objects on the retina, while compensating for refractive error.	Refractive medium that focuses light rays from near, intermediate and distant objects on the retina, while compensating for refractive error.
		Spherical & Toric	Spherical & Toric	Spherical & Toric
3.)	**INDICATION**	Correction of visual acuity in patients with myopia, hyperopia, and/or are astigmatic.	Correction of visual acuity in patients with myopia, hyperopia, and/or are astigmatic.	Correction of visual acuity in patients with myopia, hyperopia, and/or are astigmatic.
4.)	**CONTACT LENS MATERIAL**	Hydrophilic Polymer	Hydrophilic Polymer	Hydrophilic Polymer
a.	Water Content	58%	55%	58%
b.	Polymer Content	42%	45%	42%
c.	Polymer	hioxifilcon A	methafilcon A	hioxifilcon A
d.	DK Value	20	18.4	20
e.	Light Transmission	greater than 95% T	greater than 95% T	greater than 95% T

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 3 2001

American Biocurve, Inc.
c/o Mr. Martin Dalsing
MedVice Consulting, Inc.
623 Glacier Drive
Grand Junction, CO 81503

Re: K011316
Trade Name: Biocurve Soft (hioxifilcon A) Contact Lenses for Daily Wear (Spherical, Toric, Clear and Visibility Tinted, Lathe-cut)
Regulatory Number: 21CFR 886.5925
Regulatory Class: II
Product Code: 86 LPL
Dated: April 27, 2001
Received: April 30, 2001

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 (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) 594-6413. 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE STATEMENT

Device Name: **BIOCURVE SOFT (hioxifilcon A) Spherical and Toric Soft Contact Lens for Daily Wear (clear and blue visibility-handling tint, lathe-cut)**

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(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 Devices
510(k) Number K011316

Prescription Use ✓
(Per 21 CFR 801.109)

or

Over-The-Counter Use ___

(Optional Format 1-2-96)