APR 14 2000

K993489

510(k) NOTIFICATION SUMMARY

Summary Prepared: 10/12/99
Application Date: 10/14/99

Applicant/Manufacturing and Packaging:

Crystal Reflections, Int., Inc.
170 N. La Canada, Ste. 80
Green Valley, AZ 85614

(800)807-8722

Jack Carter, President

Contact Person (Submission Correspondent):

Robert Breece, O.D.
BioMed Devices Corporation
1325 Progress Drive
Front Royal, VA 22630

(540) 636-7976
Fax (540) 635-8846

Trade Name: Crystal Tinted Soft Contact Lenses

Classification Name: Lenses, Soft Contact, Daily Wear

Common Name: Soft Contact Lens

Description of CRYSTAL TINTED SOFT CONTACT LENSES:

The CRYSTAL TINTED SOFT CONTACT LENSES are available in Aqua, Amber, Royal Blue, Sky Blue, Sapphire Blue, Emerald Green, Mint Green, Green, Light Yellow, Dark Yellow, Light Red, Dark Red, Brown, Black and Orange. They are available with or without tinted centers (pupillary area). The practitioner may also choose tint intensity and custom mix colors (via consultation with CRII).

CRYSTAL TINTED SOFT CONTACT LENSES are color enhanced soft contact lenses that have been previously prescribed for a specific patient. They have been supplied to CRII by a certified supplier to be modified by a tinting process. This process uses color additives that have been supplied by a certified supplier and listed as safe for contact lenses containing hydroxyl groups in accordance with FDA color additive regulations. The color additives are used in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect. As part of the manufacturing process, the lenses containing the color additives are thoroughly washed to remove unbound reactive color additives. The manufacturing process alters and/or changes the specifications to the clear version of a contact lens by affixing a listed color reactive additive on that portion of the anterior (front) surface of the lens that corresponds to the iris.

CRYSTAL TINTED SOFT CONTACT LENSES are tinted using certified Reactive dyes listed by the FDA as approved for use with contact lenses. The lens material is modified by permanently fixing tints to the polymer using the following color additives, either alone or in combination: Reactive Blue 19, Reactive Blue 21, Reactive Yellow 86, Reactive Black 5, Reactive Red 11, Reactive Blue 163, Reactive Orange 78, Reactive Yellow 15, and Reactive Red 180.

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.

Bioburden/Toxicology Testing:

Bioburden testing was performed at NAMSA in Northwood, Ohio in February, 2000. Ten samples were tested for two types of microorganisms: aerobic bacteria and fungi. There were less than 4 CFU's recoverable for any sample, passing according to NAMSA testing standards.

All dyes to be used in the custom tinting process were mixed together and applied to (hydrophilic) soft contact lenses. The contact lenses were then subjected to the following three Toxicity Studies by the North American Science Associates Incorporated: ISO Ocular Irritation Study In the Rabbit, ISO Acute Systemic Toxicity Study in the Mouse, and Cytotoxicity Using the ISO Elution Method. All results were negative.

"Statement of Indications for Use"

Device Name: Crystal Tinted Soft Contact Lens

INDICATIONS FOR USE:

The Crystal Tinted Soft Contact Lens is indicated for daily wear to enhance and/or alter the apparent eye color.

Except for decreased light transmittance due to the tint intensity, the pre-tinted lens optical parameters remain the same as originally prescribed for the user prior to tinting. The lens may be disinfected using a chemical disinfection system only.

CRII claims the CRYSTAL TINTED CONTACT LENS that it custom tints from contact lenses that were previously prescribed for each individual patient by his/her personal eye care professional, is substantially equivalent to the following "legally marketed predicate device":

PREDICATE DEVICE:

Manufacturer:	Adventures in Colors, Inc.
Device names:	Adventure Tints, Color Enhanced Soft Contact Lens (K984098)

	Characteristic	CRYSTAL TINTED SOFT CONTACT LENS		PREDICATE DEVICE
1.)	**INDICATION**	Daily Wear, Soft (hydrophilic) contact lens		SAME
2.)	**INTENDED USE**	The CRYSTAL TINTED SOFT CONTACT LENS is indicated for daily wear to enhance and/or alter the apparent eye color.		SAME
3.)	**LENS FUNCTION**	Refractive medium that focuses light rays from near and distant objects on the retina, while compensating for refractive error.		SAME
4.)	**MATERIALS**			
a.	Polymer	Hydrophilic		SAME
b.	Additives	FDA Listed Reactive Dyes		SAME
5.)	**FDA "LISTED" COLOR ADDITIVES**	The reactive color additives are as follows: Reactive Blue 19, Reactive Blue 21, Reactive Yellow 86, Reactive Black 5, Reactive Red 11, Reactive Blue 163, Reactive Orange 78, Reactive Yellow 15 and Reactive Red 180.		SAME
a.	Uses and Restrictions	The color additives listed above may be used to color soft contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended effect.		SAME
b.	Color Additive Characteristics	The color additives are not removed by lens handling and cleaning/disinfecting procedures. The optical performance characteristics are not altered by the lens tinting process.		SAME
c.	Colors Offered	Aqua, Amber, Royal Blue, Sky blue, Sapphire Blue, Emerald Green, Mint Green, Green, Light Yellow, Dark Yellow, Light Red, Dark Red, Brown, Black and Orange		Blue, Green, Aqua, Yellow, Lavender, Brown, Ultra Violet (hot pink) and Amber
6.)	**PRODUCTION METHOD**	FDA Listed Reactive Dye molecules replace Hydroxyl (polymer) ions		SAME

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 2000

Crystal Reflections, Int., Inc.
c/o Robert Breece, O.D.
BioMed Devices Corporation
1325 Progress Drive
Front Royal, VA 22630

Re: K993489
Trade Name: CRYSTAL TINTED SOFT CONTACT LENS For Daily Wear
(tinted with Reactive Dyes)
Regulatory Class: II
Product Code: 86 LPL
Dated: April 3, 2000
Received: April 4, 2000

Dear Dr. Breece:

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) 594-4613. 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" (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, Ear, Nose and
Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

"Statement of Indications for Use"

Device Name: Crystal Tinted Soft Contact Lens

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Ey Ch, Ph.D.
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K993489

Prescription Use ✓
(Per 21 CFR 801.109)