MAY 2 7 2004

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: **K040914**

Applicant information:

Date Prepared:	April 5, 2004
Name:	**Exero Products, Inc.**
Address	623 Glacier Drive Grand Junction, CO 81503
Contact Person:	Troy Dalsing
Phone number:	970 243 5490
Official Correspondent:	Medvice Consulting, Inc. Martin Dalsing 970 243 5490

Device Information:

Device Classification:	Class II
Product Code:	LRX (0)
Classification Name:	Contact Lens Case
Trade Name:	**PolyVial / PolyPak, Contact Lens Case and Storage System Container for Ophthalmics**

Equivalent Devices:

The PolyVial / PolyPak Soft Contact Lens Case is substantially equivalent to the following predicate devices.

Predicate devices:

Alcon Contact Lens Case
Manufactured/distributed by Alcon Laboratories.
510(k) number; **K971618**

Alcon Contact Lens Case
Manufactured/distributed by Alcon Laboratories.
510(k) number; **K974281**

Paragon Lens Carrier
Manufactured/distributed by Paragon Vision Sciences.
510(k) number; **K993486, K993487**

Paragon Contact Lens Case
Manufactured/distributed by Paragon Vision Sciences.
510(k) number; **K993486**

CyberCases
Manufactured/distributed by Bausch & Lomb.
510(k) number; **K013232**

#900G (Lens Vial w/ gasket and cap)
Manufactured/distributed by Pelican Products, Inc.
510(k) number; **K030987**

Device Description:

The **PolyVial / PolyPak** by Exero Products consists of a polypropylene body, polypropylene cap, with an integrated Thermoplastic Elastomer (TPE) seal in the cap that provides a hermetically sealed container for leak proof storage of hard, RGP (Rigid Gas Permeable) fluro silicone acrylate and silicone acrylate and Soft (hydrophilic) contact lenses during chemical disinfection. The storage system consists of two removable side-by-side PolyVials that rest on a PolyPak that clearly identifies the left from the right. The PolyVials are closed by simply pressing the cap down onto the base that engages the Thermoplastic Elastomer integrated in the cap to the flange portion of the polypropylene base.

Performance:

The PolyVial / PolyPak contact lens case is designed to have an overflow capacity of 3.2ml in each lens well. This will be sufficient volume to assure that the contact lens will remain immersed under use conditions.

Intended Use:

PolyVial / PolyPak Contact Lens Case storage system by Exero Products is indicated for storage of hard, RGP (Rigid Gas Permeable) fluro silicone acrylate and silicone acrylate and Soft (hydrophilic) contact lenses during chemical disinfection.

Description of Safety:

A series of *in-vitro* and *in-vivo* toxicological and chemical studies were performed to access the safety and effectiveness of the PolyVial / PolyPak Contact Lens Cases and Storage System Containers by Exero Products in accordance with the guidelines set forth in the FDA's May 1, 1997 **Guidance for Industry – Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products.** All studies were conducted in compliance with Good Laboratory Practice Regulation for Nonclinical Laboratory Studies. A summary of these results from the studies is presented below.

Toxicology.

In-Vitro Cytotoxicity ISO Elution (MEM Extract): ISO 10993-5 was conducted in accordance with standards on test article. The test article meets the requirements of the ANSI/AAMI/ISO Elution Test and was considered noncytotoxic.

In-Vitro Cytotoxicity ISO Agar Diffusion (Direct): ISO 10993-5 / USP 27 was conducted in accordance with standards on test article. The test article meets the requirements of the USP and ISO Agarose Overlay Method test and was considered noncytotoxic.

In Vivo USP Systemic Injection Toxicity: The lens material meets the requirements of the systemic injection test and is considered non-toxic.

In Vivo Ocular Irritation Test (ISO): ISO 10993-10 Acute ocular irritation test was performed and did not cause a positive irritation response to the eyes of the test animals.

Substantial Equivalence:

PolyVial / PolyPak Contact Lens Case and Storage System Containers by Exero Products is substantially equivalent in terms of indications for use, safety and effectiveness to the predicate devices as previously depicted, and *does not raise* different questions of safety and effectiveness than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2004

Medvice Consulting, Inc.
c/o Martin Dalsing
623 Glacier Drive
Grand Junction, CO 81503

Re: K040914
Trade/Device Name: PolyVial / PolyPak, Contact Lens Case and Storage System Container for Ophthalmics
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LRX
Dated: April 5, 2004
Received: April 8, 2004

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 Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

INDICATIONS FOR USE STATEMENT

Device Name: **PolyVial / PolyPak, Contact Lens Case and Storage System Container for Ophthalmics**

INDICATIONS FOR USE:

PolyVial / PolyPak Contact Lens Case storage system by Exero Products is indicated for storage of hard, RGP (Rigid Gas Permeable) fluro silicone acrylate and silicone acrylate and Soft (hydrophilic) contact lenses during chemical disinfection

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

Daniel W. C. Brown, Ph.D.

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

510(k) Number K040914