JUN 2 8 2006

FOI Summary K060924 June 6, 2006

510(k) SUMMARY

K060924

JSZ MultiAction GP Contact Lens Solution
JSZ Wetting/Rewetting Eyedrop

This summary uses the format provided in 21 CFR 807.92:

(a)(1). **Submitter:**

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President
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CHICAGO IL 60601

Phone 312-553-0828
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Summary prepared: June 6, 2006

(a)(2) **Device Trade Name:** **JSZ MultiAction GP Contact Lens Solution**
JSZ Wetting/Rewetting Eyedrop

Device Common Name: Rigid Gas Permeable contact lens solution
Contact lens Wetting/Rewetting Eyedrop

Device Classification Name:

JSZ MultiAction GP Contact Lens Solution:
Products, Contact Lens Care, Rigid Gas Permeable (MRC)

JSZ Wetting/Rewetting Eyedrop:
Accessories Soft Lens Products (LPN) and Products, Contact Lens Care, Rigid Gas Permeable (MRC)

(a)(3) **Identification of Predicate Device:**

The **JSZ MultiAction GP Contact Lens Solution** product is substantially equivalent to other currently marketed rigid gas permeable (GP) contact lens care multipurpose solutions, such as Optimum Cleaning, Disinfecting and Storage Solution, Boston Simplus Multiaction Solution, and Sauflon Delta Plus Multiaction Solution.

The **JSZ Wetting/Rewetting Eyedrop** is substantially equivalent to other currently marketed wetting/rewetting drops for use with contact lenses, such as Complete Blink-n-Clean Lens Drops.

Both the **JSZ MultiAction GP Contact Lens Solution** and the **JSZ Wetting/Rewetting Eyedrop** are identical in composition to the **JSZ-Multipurpose Solution** previously cleared for market in K050517, which is also identical to Sauflon Delta Plus Multiaction Solution.

(a)(4) **Device Description:**

Both products are sterile, isotonic solutions that contain poloxamer, sodium phosphate buffer, sodium chloride, and disodium edetate; preserved with polyhexanide 0.0001%. Contain no chlorhexidine, no thimerosal, nor any other mercury containing products.

The products are packaged in sizes appropriate to their intended uses: **JSZ MultiAction GP Contact Lens Solution** in 2oz (60ml) and 4oz (120ml) bottles, **JSZ Wetting/Rewetting Eyedrop** in 0.5oz (15ml) and 1oz (30ml) bottles.

(a)(5) **Intended Use (Indications for Use):**

The **JSZ MultiAction GP Contact Lens Solution** is indicated for use in cleaning, rinsing, chemical (not heat) disinfection, storage and conditioning of rigid gas permeable contact lenses, including fluoro-silicone acrylate and silicone acrylate lenses, as recommended by your eye care practitioner.

JSZ Wetting/Rewetting Eyedrop is indicated to rewet soft (hydrophilic) and condition and wet rigid gas permeable contact lenses, including fluoro-silicone acrylate and silicone acrylate lenses, before application and during lens wear. The product may be used with daily wear or extended wear lenses and with disposable lenses or lenses prescribed for frequent replacement.

(a)(6) **Comparison of Technological Characteristics:**

No changes have been made to the product formulation subject to this application. All technical information is contained in K050517.

b)(1) **Discussion of Nonclinical:**

No new data have been submitted in this application. All information is contained in K050517.

(b)(2) **Discussion of Clinical Data:**

No new data have been submitted in this application. Based on the identity of the solution to the previously cleared solutions, no clinical data was required.

(b)(3) **Conclusions Drawn from Data Supporting Equivalence Determination:**

This application presents new labeling for the product. There were no changes in

the product formulation and no new data were presented. The products are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 28 2006

Szabocsik and Associates
c/o Mr. John M. Szabocsik
203 North Wabash Ave., Suite 1200
Chicago, IL 60601

Re: K060924
Trade/Device Name: JSZ MultiAction GP Contact Lens Solution
Regulation Number: 21 CFR 886.5918
Regulation Name: Rigid Gas Permeable Contact Lens Care Products
Regulatory Class: II
Product Code: MRC

Trade/Device Name: JSZ Wetting/Rewetting Eyedrop
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) Contact Lens Care Products
Regulatory Class: II
Product Code: LPN; MRC
Dated: June 7, 2006
Received: June 8, 2006

Dear Mr. Szabocsik:

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for 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

510(k) NUMBER (IF KNOWN) K060924

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Indications for Use

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(PLEASE DO NOT 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 K060924

Prescription Use ___ OR Over-The-Counter-Use ✓
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

INDICATIONS FOR USE STATEMENT

510(k) NUMBER (IF KNOWN) K060924

Device Name: **JSZ Wetting/Rewetting Eyedrop**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary Ann Silva

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

510(k) Number K060924

Prescription Use ___ OR Over-The-Counter-Use ✓
(Per 21 CFR 801.109)
(Optional Format 1-2-96)