K102154

JAN 2 1 2011

December 14, 2010

510(k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS

TYRO™-97 (hofocon A) and ONSI™-56 (onsifocon A) Rigid Gas Permeable Contact Lenses for Daily Wear

1. **SUBMITTER INFORMATION:**

The Lagado Corporation
2890 South Tejon St
Englewood, CO 80110

Contact: John M. Szabocsik, Ph.D.
Official agent
Szabocsik and Associates
203 N. Wabash, Ste 2208
Chicago, IL 60601
(312) 553-0828

2. **DATE PREPARED:** December 13, 2010

3. **DEVICE NAME:**

Classification Name: rigid gas permeable (hydrophilic) contact lenses

Proprietary Names: TYRO™-97 (hofocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens

ONSI™-56 (onsifocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens

4. **CLASSIFICATION:**

Class II (Performance Standards)
Classification: HQD
21 CFR 886.5916 (b) (1)
Rigid Gas Permeable Contact Lens for Daily Wear

5. **DESCRIPTION OF DEVICES:**

The TYRO™ 97 (hofocon A) Rigid Gas Permeable lens material, hofocon A, is a polymer of trifluoroethyl methacrylate and silicone methacrylate, with no methyl methacrylate. The blue tinted lenses contain D&C Green No. 6; the green lenses contain D&C Green No 6 and CI Solvent Yellow 18; the gray lenses contain D&C Green No 6, D&C Violet No. 2, and CI Solvent Yellow 18; the blue-UV lenses contain D&C Green No 6 and a UV absorber, [2-(2'-hydroxy-5'-methacryloxyethylphenyl)-2H-benzotriazole. The colorants are used in quantities approved for use in contact lenses and proportions required to obtain the desired color.

The physical properties of the hofocon A lenses are as follows:

Typical Property	Test Value

Hardness	D/82 (Shore HardnessUnits)
Water Content	<0.2%
Wetting Angle	23.3E (sessile drop method)
Oxygen Permeability	97 ANSI units
Dimensional Stability	Stable
Refractive Index	1.440
Specific Gravity	1.087
Flexural Strength	3952 psi

The ONSI™-56 (onsifocon A) Rigid Gas Permeable lens material, onsifocon A,is a polymer of trifluoroethyl methacrylate polymer with tris (trimethylsiloxy) methacryloxypropylsilane 3-trimethoxysilylpropylmethacrylate methacrylic acid 1,3-bis(3-methacryloxypropyl)tetrakis(trimethylsiloxy)disiloxane ethylene glycol dimethacrylate 2-hydroxyethyl methacrylate N-vinylpyrrolidone.

The blue tinted onsifocon A lenses contain D&C Green No. 6; the green lenses contain D&C Green No 6 and CI Solvent Yellow 18; the gray lenses contain D&C Green No 6, D&C Violet No. 2, and CI Solvent Yellow 18; the blue-UV lenses contain D&C Green No 6 and a UV absorber, [2-(2'-hydroxy-5'-methacryloxyethylphenyl)-2H-benzotriazole. The colorants are used in quantities approved for use in contact lenses and proportions required to obtain the desired color.

The physical properties of onsifocon A lenses are as follows:

Typical Property	Test Value
Hardness	D/85 (Shore HardnessUnits)
Water Content	<1.0%
Wetting Angle	7.25° ± 1.55 (sessile drop method)
Oxygen Permeability	56.2 ANSI units
Dimensional Stability	Stable
Refractive Index	1.452
Specific Gravity	1.206
Flexural Strength	3952 psi

6. INDICATIONS FOR USE:

The TYRO™-97 (hofocon A) and ONSI™-56 (onsifocon A) Rigid Gas Permeable Contact Lenses are indicated for daily wear for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic, hyperopic or presbyopic and which may exhibit corneal astigmatism. Also, the lenses may be prescribed in otherwise non-diseased eyes that require a gas permeable contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g., LASIK) surgery.

The lenses may be disinfected only by using chemical disinfection

7. SAFETY AND SUBSTANTIAL EQUIVALENCE:

The safety and efficacy of the TYRO™-97 (hofocon A) and ONSI™-56 (onsifocon A) Rigid Gas Permeable Contact Lenses were demonstrated in 510(k) Premarket Notifications as follows: K052507 - SE Decision Date 02-NOV-05 and K033599 - SE Decision Date 16-SEP-04, respectively.

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The TYRO™-97 (hofocon A) and ONSI™-56 (onsifocon A) Rigid Gas Permeable Contact Lenses are substantially equivalent to the BOSTON ES (enflufocon A), BOSTON EO (enflufocon B) and BOSTON XO (hexafocon A) Rigid Gas Permeable Contact Lenses indicated for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery K053124 - SE Decision Date 30-JAN-06.

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SUBSTANTIAL EQUIVALENCE

	Hofocon A	Onsifocon A	Hexafocon B (Boston XO)	Enflufocon A (Boston ES)	Enflufocon B (Boston EO)
Water Content	<0.2%	<1.0%	<1%	<1%	<1%
O_2 Permeability	Fatt Method: D_k units=97 x 10^{-11} $(cm^3O_2)(cm)/[(sec)(cm^2)(mmHg)]$ @ 35°C	Fatt Method: D_k units=56.5 x 10^{-11} $(cm^3O_2)(cm)/[(sec)(cm^2)(mmHg)]$ @ 35°C	Fatt Method: D_k units=141 x 10^{-11} $(cm^3O_2)(cm)/[(sec)(cm^2)(mmHg)]$ @ 35°C	Fatt Method: D_k units= 18 x 10^{-11} $(cm^3O_2)(cm)/[(sec)(cm^2)(mmHg)]$ @ 35°C	Fatt Method: D_k units= 58 x 10^{-11} $(cm^3O_2)(cm)/[(sec)(cm^2)(mmHg)]$ @ 35°C
Refractive Index	1.440	1.452	1.415	1.443	1.420
Hardness	D/82 (Shore)	D/85 (Shore)			
Specific Gravity	1.087	1.206	1.27	1.22	1.23
Wetting Angle	estimate <25°	7.25 ± 1.55°	49°	52°	49°
Mechanical (flexural) Strength	3952 psi	2698 psi			
Light Tansmittance	Clear >95%T Blue >70% T Green>70% T	Clear>95%T Blue>70% T Green>70%T Grey>70% T Blue-violet>70% T Blue-UV>70%T(400-780nm) 0%T (200-380nm)	>92%	>85%	>85%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Szabocsik and Associates
c/o Dr. John M. Szabocsik
203 North Wabash Avenue
Suite 2208
Chicago, Illinois 60601

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Re: K102154
Trade/Device Name: TYRO-97 (hofocon A), ONSI™ - 56 (onsifocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid Gas Permeable Contact Lens for Daily Wear
Regulatory Class: Class II
Product Code: HQD
Dated: December 20, 2010
Received: December 23, 2010

Dear Dr. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Kesia Alexander

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

Enclosure

December 14, 2010

510(k) NUMBER (IF KNOWN)

DEVICE NAME TYRO™-97 (hofocon A) and ONSI™-56 (onsifocon A) Rigid Gas Permeable Contact Lenses for Daily Wear

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)

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

(Optional Format 1-2-96)

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(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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