K103561

510(k) summary

MENICON Z ™ (tisilfocon A) RIGID GAS PERMEABLE CONTACT LENSES

February 2011

FEB - 3 2011

1. **Applicant Information**

Menicon Co., Ltd.
21-19, Aoi 3-chome,
Naka-ku, Nagoya, Aichi 460-0006
JAPAN
Contact Person: Takahiro Ochi
Telephone No.: +81-52-935-1676
Fax No.: +81-52-935-1633

E-mail: t-ochi@menicon-net.co.jp

2. **Device Information**

Classification name: Lenses, Rigid Gas Permeable, Daily Wear Contact Lenses
Device classification: Class II
Regulation number: 21 CFR 886.5916
Product code: HQD
Proprietary name: Menicon Z (tisilfocon A) Rigid Gas Permeable Contact Lenses

3. **Predicate Devices**

Menicon claims substantial equivalence of the Menicon Z™ (tisilfocon A) to the following predicate devices.

1. Menicon Z ™ (tisilfocon A) Rigid Gas Permeable Contact Lenses (K962006, K970019, K081443)
2. Boston XO_2 (hexafocon B) Rigid Gas Permeable Contact Lenses (K071266)
3. Boston XO (hexafocon A) Rigid Gas Permeable Contact Lenses (K071043)
4. Boston Equalens II (oprifocon A) (K022128) (Rigid Gas Permeable Contact Lenses

4. **Description of device**

The Menicon Z™ lens material, tisilfocon A is a thermoset copolymer derived from fluoromethacrylate and siloxanylstyrene, bound by crosslinking agents.
The lens is tinted light blue with color additive D&C Green No. 6 (21 CFR 74.3206).
Also, UV absorber (benzotriazol) is added.

5. **Indications for use**

Menicon Z™ (tisilfocon A) spherical, aspheric, prism ballast toric and prism ballast multifocal lenses in all diameters are indicated for daily wear for the correction of refractive error (myopia, hyperopia, presbyopia and/or astigmatism) in aphakic and non-aphakic persons with non-diseased eyes.

Menicon Z™ (tisilfocon A) spherical, aspheric, non-prism ballast toric and non-prism ballast multifocal lenses in diameters ≤ 12.0 mm are indicated for extended wear (from 1 to 30 days between removals for cleaning and disinfection of the lenses, as recommended by the eyecare professional) for the correction of refractive error (myopia, hyperopia, presbyopia and/or astigmatism) in non-aphakic persons with non-diseased eyes.

The lens may be prescribed in spherical and aspheric powers ranging from -25.00 D to +25.00 D for daily wear and -25.00 D to +8.00 D for up to 30 days extended wear. Toric lenses are designed to correct up to 5.00 D of astigmatism and multifocal lenses to provide up to +3.00 D of reading add power for up to 30 days extended wear.

The lenses may be prescribed for daily wear in otherwise non-diseased eyes that require a rigid 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 lens may be disinfected using a chemical disinfection system only.

6. **Description of safety and substantial equivalence**

The safety and efficacy of the Menicon Z ™ (tisilfocon A) Rigid Gas Permeable Contact Lens material was demonstrated in 510(k) Premarket Notifications as follows.

- K962006 cleared on October 9, 1996
- K970019 cleared on March 25, 1997 (multifocal designs)
- K081443 cleared on September 23, 2008 (irregular corneas/postsurgical)

Menicon Z™ (tisilfocon A) Rigid Gas Permeable Contact Lenses are substantially equivalent to

- Menicon Z (tisilfocon A) Rigid Gas Permeable Contact Lenses for already approved indications and designs (as noted above).
- Boston XO_2 (hexafocon B) (K071266), Boston XO (hexafocon A) (K071043) and Boston Equalens II (oprifocon A) (K022128) (Rigid Gas Permeable Contact Lenses for indications for use, material properties, lens designs in diameters up to 21 mm, manufacturing/packaging methods and biocompatibility.

The indication for use for the lenses is for daily wear for the correction of refractive error (myopia, hyperopia, presbyopia and/or astigmatism) in aphakic and non-aphakic persons with non-diseased eyes. Additionally, the Menicon Z, Boston XO and Boston XO_2 lenses may be prescribed for daily wear in otherwise non-diseased eyes that require a rigid 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 following table compares the physical/optical properties of the Menicon Z material with the predicate lens materials:

Property	Menicon Z	Boston XO	Boston XO_2	Boston Equalens II
Specific Gravity	1.20	1.27	1.19	1.24
Refractive Index	1.436	1.425	1.424	1.423
Visible Light Transmittance	>95%	92% Average	83-90%	≥70%
Water Content	<0.5%	<1%	<1%	<1%
Oxygen Permeability (Dk***)	189* 163**	140* 100**	141	85**

* gas to gas method

** polarographic method (ISO)

*** (cm2/sec)(mL O2 / (mL x mmHg) @35℃ (unit)

Substantial equivalence is further supported by the fact that the Menicon Z and predicate devices are composed of fluoro silicone acrylate polymers, have similar manufacturing and packaging methods, are provided non-sterile and have demonstrated biocompatibility based on the requirements stated in the Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses, May 1994.

7. **Clinical data:**

Clinical study data for the Menicon Z™ (tisilfocon A) material in large diameters have been deemed as not necessary in support of this clearance, as no new or additional questions of safety or effectiveness have been raised.

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

Foresight Regulatory Strategies, inc.
c/o Dr. Beverly D. Venuti, R.A.C.
Staff Consultant
187 Ballardvale Street, Suite 180
Wilmington, MA 01887-4461

FEB - 3 2011

Re: K103561
Trade/Device Name: Menicon Z™ (tisilfocon A) Rigid Gas Permeable Contact Lenses
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid Gas Pemeable Contact Lens
Regulatory Class: Class II
Product Code: HQD
Dated: December 3, 2010
Received: December 6, 2010

Dear Dr. Venuti:

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,

Kesia Alexander

for 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

Indications for Use

510(k) Number (if known): K103561

Device Name: Menicon Z™ (tisilfocon A) Rigid Gas Permeable Contact Lenses

Indications for Use:

Menicon Z™ (tisilfocon A) spherical, aspheric, prism ballast toric and prism ballast multifocal lenses are indicated for daily wear for the correction of refractive error (myopia, hyperopia, presbyopia and/or astigmatism) in aphakic and non-aphakic persons with non-diseased eyes.

Menicon Z™ (tisilfocon A) spherical, aspheric, non-prism ballast toric and non-prism ballast multifocal corneal lenses are indicated for extended wear (from 1 to 30 days between removals for cleaning and disinfection of the lenses, as recommended by the eyecare professional) for the correction of refractive error (myopia, hyperopia, presbyopia and/or astigmatism) in non-aphakic persons with non-diseased eyes.

The lenses may be prescribed for daily wear in otherwise non-diseased eyes that require a rigid 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 lens may be prescribed in spherical and aspheric powers ranging from -25.00 D to +25.00 D for daily wear and -25.00 D to +8.00 D for up to 30 days extended wear. Toric lenses are designed to correct up to 5.00 D of astigmatism and multifocal lenses to provide up to +3.00 D of reading add power for up to 30 days extended wear.

The lens may be disinfected using a chemical disinfection system only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anna Pollell

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

510(k) Number K103561