

510(k) Summary

K972443

AUG 22 1997

Applicant's Name and Address: Menicon Co., Ltd.
21-19, Aoi 3-Chome
Naka-ku, Nagoya 460
Japan
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Contact Person: Cristina M. Schnider, OD, MSc, FAAO
Menicon U.S.A. Inc.
333 West Pontiac Way
Clovis, CA 93612
Phone (209) 292-2020 x114
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Summary Prepared June 1997

Trade Name:

This process change applies to Menicon Rigid Gas Permeable (RGP)
Contact Lenses:

Menicon SF-P™ (melafocon A) Rigid Gas Permeable Contact Lens
Menicon Z™ (tisilfocon A) Rigid Gas Permeable Contact Lens

Device Generic Name:

melafocon A
tisilfocon A

Classification Name:

Contact lens, rigid gas permeable

Common/Usual Name

Fluoro silicone acrylate rigid gas permeable contact lens

Predicate Device:

Menicon SF-P (melafocon A) and Menicon Z (tisilfocon A) Rigid Gas
Permeable Contact Lenses under dry storage

Device Description:

The Menicon SF-P (melafocon A) RGP lens is a thermoset copolymer derived from fluoro-methacrylate, siloxanymethacrylate and methacrylic acid with water absorbance of less than 0.5% by weight. The lens is available in blue tint. The blue tinted lens contains D&C Green No. 6 as the color additive.

The Menicon Z (tisilfocon A) RGP lens is a thermoset copolymer derived from fluoro-methacrylate and siloxanylstyrene, bound by crosslinking agents. Lens colors available are light blue and violet. The blue lens is tinted with color additive D & C Green No. 6 and the violet lens contains the color additives D & C Green No. 6 and D & C Violet No. 2. Also, UV absorber is added.

Solution used for packaging the Menicon RGP lenses:

BARNES-HIND® ComfortCare® GP WETTING & SOAKING SOLUTION, which contains edetate disodium and chlorhexidine gluconate as preservatives.

Indications for Use:

The Menicon SF-P (melafocon A) Contact Lens is 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. The lens may be disinfected using a chemical disinfection system only.

The Menicon Z (tisilfocon A) Contact Lens is 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. The lens may be disinfected using a chemical disinfection system only.

Substantial Equivalence:

Menicon SF-P and Menicon Z RGP lenses under wet storage for up to 30 days are substantially equivalent to the Menicon SF-P and Menicon Z RGP lenses under dry storage.

The applicant performed non-clinical stability and microbiology testing on the Menicon RGP lenses stored wet for 30 days. This testing in conjunction with toxicology testing on the shipping case plastics supports the claim of substantial equivalence to Menicon RGP lenses shipped and stored in the dry state.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cristina M. Schnider, O.D., M.Sc., F.A.A.O.
Director of Professional Relations and Clinical Affairs
Menicon USA, Inc.
333 West Pontiac Way
Clovis, CA 93612-5613

AUG 22 1997

Re: K972443
Trade Names: Menicon SF-P™ (melafocon A) Rigid Gas Permeable Contact Lens for
Daily Wear (Visibility tinted, Lathe-cut, Wet shipping)

Menicon Z™ (tisilfocon A) Rigid Gas Permeable Contact Lens for Daily
Wear (Visibility tinted with UV absorber, Lathe-cut, Wet shipping)

Regulatory Class: II
Product Code: 86 HQD
Dated: June 27, 1997
Received: June 30, 1997

Dear Dr. Schnider:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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 devices 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.

Page 2 - Cristina M. Schnider, O.D., M.Sc., F.A.A.O.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/dsmamain.html>".

Sincerely yours,


for A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K972443

Device Name: Menicon SF-P™ and Menicon Z™ Rigid Gas Permeable Contact Lenses

Indications for Use:

The Menicon SF-P (melafocon A) Contact Lens is 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. The lens may be disinfected using a chemical disinfection system only.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Karen F. Warburton

(Division Sign-Off)

Division of Ophthalmic Devices

510(k) Number K972443

Prescription Use
(Per 21 CFR 80.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)