APR 0 3 2013

K130285

510(k) Summary

MENICON PROGENT LARGE DIAMETER CONTACT LENS CASE FOR RIGID GAS PERMEABLE CONTACT LENSES

February 22, 2013

1. Applicant Information

Lagado Corporation
Contact Person: Mark Allen
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Date Prepared: February 22, 2013

2. Device Information

Classification name:	Rigid gas permeable contact lens care products
Device classification:	Class II
Regulation number:	21 CFR 886.5918
Product code:	LRX
Proprietary name:	Menicon Large Diameter Contact Lens Case For Rigid Gas Permeable Contact Lenses

3. Predicate Devices

Lagado Corporation claims substantial equivalence to K991206 Bonasse Non-Vented Barrel Style Contact Lens Case and the Progent SP Vial cleared in 510(k) K122273.

4. Description of Device

The Menicon Progent Large Diameter Contact Lens Case is a non-vented barrel style contact lens case. It consists of a clear polycarbonate (PC) cylinder with acrylonitrile-butadiene-styrene (ABS) copolymer non-vented screw cap and lens holder/basket. Each lens basket is molded with a letter, "L" or "R", for ease in proper lens identification. The left lens basket is also colored grey to assist patients who are not currently wearing their contact lenses. The lens case is capable of holding the 10 mL of Menicon Progent Protein Remover A/B mixed solution for effective protein removal.

5. Indications for Use

Menicon Progent Large Diameter Contact Lens Case is only intended for use with the Menicon Progent Protein Remover for Rigid Gas Permeable (RGP) Contact Lenses.

The Menicon Progent Large Diameter Contact Lens Case provides an alternative lens case to hold large diameter lenses (11 mm to 23 mm) during the Menicon Progent Protein Remover treatment. The case is not intended for disinfection (chemical, heat or peroxide). The case is not intended for lens storage.

6. Substantial Equivalence

The claim of substantial equivalence to the previously cleared K991206 Bonasse Non-Vented Barrel Style Contact Lens Case is supported by the following Comparison of Characteristics in Table 1.

The Progent Large Diameter Contact Lens Case is also equivalent to the cleared Progent SP Vial cleared in K122273.

Based upon the comparison the Menicon Progent Large Diameter Contact Lens Case is substantially equivalent to the predicate devices. The contact lens cases are similar in design and volume. The lens cases are manufactured from similar materials that have been proven to be safe for use. The lens cases can be used for lens treatments, such as chemical disinfection for predicate device or protein removal for the Menicon Progent Cases.

Therefore, Progent Large Diameter Contact Lens Case is substantially equivalent to the predicate devices.

Table 1 Comparison of Characteristics			
Manufacturer	**Bonasse Enterprise Company, Ltd.**	**Bonasse Enterprise Company, Ltd.**	**Menicon Pharma**
Device Name	**Contact Lens Case**	**Contact Lens Case**	**Contact Lens Case**
Model Name	**BC 790**	**BC 760-1**	**Not Applicable**
Trade Name	**Menicon Progent Large Diameter Contact Lens Case**	**Bonasse Barrel Style Lens Case BC 760-1**	**Barrel Style Lens Case**
510(k)	**To Be Determined**	**K991206**	**K122273**
Classification	**Ophthalmic**	**Ophthalmic**	**Ophthalmic**
Product Code	**LRX**	**LRX**	**LRX**
Regulation Number	**21 CFR 886.5918**	**21 CFR 886.5918**	**21 CFR 886.5918**
Class	**II**	**II**	**II**
Intended Use	**For Storage of RGP Contact Lenses during lens treatment (protein removal), Not for use with heat, chemical or peroxide disinfection systems.**	**For Storage of soft, hard and RGP contact lenses during lens treatment (chemical disinfection), Not for use with heat or peroxide disinfection systems.**	**For Storage of RGP contact lenses during lens treatment (protein removal), Not for use with heat, chemical or peroxide disinfection systems.**
Materials	**Clear Plastic Vial (PC) White Plastic screw top lid* (ABS) White and Grey plastic lens baskets/holder (ABS)**	**Clear Plastic Vial, White Plastic screw top lid* (ABS) White plastic lens baskets/holder (ABS)**	**Clear Plastic Vial, Green Plastic screw top lid* Clear plastic lens holder**
Volume	**10 mL**	**10 mL**	**10 mL**
Biocompatability	**Components used in this lens case have been evaluated in accordance with Part 10993 of the ISO standard for Biological Evaluation. Test results indicate the test articles meet the ISO standard**	**Biocompatability testing by a third party laboratory demonstrated the materials are safe for use in contact lens storage and disinfection****	**Biocompatability testing by a third party laboratory demonstrated the materials are safe for use in contact lens storage and disinfection**
*Non Vented Screw Top Lids			
**Source K991206 Summary of Safety and Effectivenes			
PC - Polycarbonate, ABS- acrylonitrile-butadiene-styrene copolymer			

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 3, 2013

The Lagado Corporation
% Ms. Ellen M. Beucler
Vice President
Foresight Regulatory Strategies, Inc.
187 Ballardvale Street, Suite 180
Wilmington, MA 01887-4461

Re: K130285
Trade/Device Name: Menicon Progent Large Diameter Contact Lens Case
Regulation Number: 21 CFR 886.5918
Regulation Name: Rigid gas permeable contact lens care products
Regulatory Class: Class II
Product Code: LRX
Dated: January 31, 2013
Received: February 5, 2013

Dear Ms. Beucler:

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 Y. Alexander -S

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

Enclosure

Lagado Corporation

Indications for Use

510(k) Number (if known): **K130285**

Device Name: Menicon Progent Large Diameter Contact Lens Case

Indications for Use:

Menicon Progent Large Diameter Contact Lens Case is only intended for use with the Menicon Progent Protein Remover for Rigid Gas Permeable (RGP) Contact Lenses.

The Menicon Progent Large Diameter Contact Lens Case provides an alternative lens case to hold large diameter lenses (11 mm to 23 mm) during the Menicon Progent Protein Remover treatment. The case is not intended for disinfection (chemical, heat or peroxide). The case is not intended for lens storage.

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)

Mridulika Virmani -S

Digitally signed by Mridulika Virmani -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13000903 15, cn=Mridulika Virmani -S
Date: 2013.04.01 11:14:17 -04'00'

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