**510(k) Summary**

**MENICON NECT**
**CONTACT LENS CASE**
**July 17, 2013**

## 1. Applicant Information


| | |
|---|---|
| Menicon Nect Co., Ltd: | 12-7, Biwajima 3, Nishi-ku,<br>Nagoya 451-0053, JAPAN |
| Contact Person: | Mr. Shinji Tanaka |
| Telephone No.: | +81-52-908-2472 |
| Fax No.: | +81-52-529-2465 |
| E-mail: | stanaka@meniconnect.co.jp |
| Date Prepared: | July 17, 2013 |


AUG 0 6 2013

## 2. Device Information

| | |
|---|---|
| Classification name: | Contact Lens Care Products |
| Device classification: | Class II |
| Regulation number: | 21 CFR 886.5918 (Rigid Gas Permeable Contact Lenses)<br>21 CFR 886.5928 (Soft (hydrophilic) Contact Lenses) |
| Product code: | LRX |
| Proprietary name: | Menicon Nect Contact Lens Case |

## 3. Predicate Devices

Menicon Nect claims substantial equivalence to K121030 Sacks Holdings, Inc. Contact Lens Storage Case cleared by the Food and Drug Administration on July 6, 2012.

## 4. Description of Device

The Menicon Nect Contact Lens Case consists of a molded dual compartment base unit and two screw caps. Both the base unit and screw caps are made from Polypropylene resin. The right screw cap is marked "R" and has a blue tint to assist patients who are not currently wearing their contact lenses. The lens compartments are of sufficient volume to allow contact lenses to be fully immersed during lens disinfection. The case is available in two models, one with ribs in the lens case wells and one without ribs in the lens case wells.

## 5. Indications for Use

Menicon Nect Contact Lens Case is indicated for storage during chemical disinfection of soft (hydrophilic), rigid gas permeable and hard contact lenses. This case is for use during chemical disinfection only. Not to be used with heat disinfection.

## 6. Performance Data

Non-Clinical Data

Biocompatibility tests were conducted on the plastic components in accordance with ISO Part 10993 Biological Evaluation of Medical Devices. Testing included Cytotoxicity, Systemic Toxicity and Ocular Irritation. The test results indicate the components are safe for the intended use.

Clinical Data

Clinical studies were unnecessary for this application. Lens care solutions used with this contact lens case are already cleared for use as cleaning, rinsing, disinfection and storage solutions for soft (hydrophilic), rigid gas permeable and hard contact lenses.

Conclusion

Based upon the test data presented, the Menicon Nect Contact Lens Case is as safe, as effective and performs as well as the predicate device. A comparison of the new device and the predicate device is presented in Table 1.

## 7. Substantial Equivalence

The claim of substantial equivalence to the previously cleared K121030 Sacks Holdings, Inc. Contact Lens Storage Case is supported by the Comparison of Characteristics in Table 1.

7. **Substantial Equivalence** (continued)

Based upon the comparison the Menicon Nect Contact Lens Case is substantially equivalent to the K121030 Sacks Holdings, Inc. Contact Lens Storage Case. The contact lens cases are similar in design and volume. Both lens cases are manufactured from similar materials that have been proven to be safe for use. Both lens cases can be used for lens chemical disinfection treatments.

Therefore, Menicon Nect Contact Lens Case is substantially equivalent to the predicate device.

| Table 1 Comparison of Characteristics | | |
|---|---|---|
| | Menicon Nect Co., Ltd. | Sacks Holdings, Inc. |
| Device Name | Contact Lens Case | Contact Lens Storage Case |
| Trade Name | Menicon Nect Contact Lens Case | Contact Lens Case |
| 510(k) | K131875 | K121030 |
| Classification | Ophthalmic | Ophthalmic |
| Product Code | LRX | LRX |
| Regulation Number | 21 CFR 886.5918<br>21 CFR 886.5928 | 21 CFR 886.5928 |
| Class | II | II |
| Intended Use | For storage during chemical disinfection of soft (hydrophilic), rigid gas permeable and hard contact lenses. This case is for use during chemical disinfection only. Not to be used with heat disinfection. | For storage during chemical disinfection of soft (hydrophilic), rigid gas permeable and hard contact lenses. This case is for use during chemical disinfection only. Not to be used with heat disinfection. |
| Disinfection Type | Chemical; Not Heat | Chemical; Not Heat |
| Design | Case Bottom with screw on caps The letter "R" embossed on the right cap. Right and Left caps are contrasting colors. | Case Bottom with screw on caps The letter "R" embossed on the right cap. Right and Left caps are contrasting colors. |
| Sterilization | Not Sold Sterile | Not Sold Sterile |
| Materials | Polypropylene resin used for the lens case base and screw top caps | Polypropylene resin used for the lens case base and screw top caps |
| Volume | 3.6 mL | 3.8 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 | 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 |

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

August 6, 2013

Menicon Nect Co., Ltd.
c/o Ms. Ellen Beucler
Vice President
Foresight Regulatory Strategies, Inc.
187 Ballardvalle Street, Suite 180
Wilmington, MA 01887-4461

Re: K131875
Trade/Device Name: Menicon Nect Contact Lens Case
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LRX
Dated: July 17, 2013
Received: July 19, 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 contact 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. 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 B. Eydelman. M.D.
Director
Division of Ophthalmic and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

# Indications for Use

**510(k) Number (if known):** K131875

**Device Name: Menicon Nect Contact Lens Case**

**Indications for Use:**

Menicon Nect Contact Lens Case is indicated for storage during chemical disinfection of soft (hydrophilic), rigid gas permeable and hard contact lenses. This case is for use during chemical disinfection only. Not to be used with heat disinfection.

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

Jeffrey M. Brocious -S
2013.08.23 10:03:48 -04'00'

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



510(k) Number: K131875