K121030

510(k) SUMMARY

Sacks Holdings, Inc.

Contact Lens Storage Case

JUL 6 2012

1.0 Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Sacks Holdings, Inc.
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Rancho Santa Fe, CA 92067
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Contact Person: Devin Chodorow

Date Prepared: July 5, 2012

2.0 Applicant Device Information
Trade Name: Contact Lens Case
Common Name: Contact Lens Case
Classification Name: Case, Contact Lens
Device Class II
Product Code: LRX
Regulation Number: 886.5928

3.0 Predicate Devices
Trade Name: i-Promotions Contact Lens Case
Applicant: i-Promotions, Inc.
Classification Name: Case, Contact Lens
Device Class II
Product Code: LRX
Regulation Number: 886.5928
510(k) Number: K042578

4.0 Device Description:
The applicant contact lens case is a lens care product used by the contact lens wearer or practitioner for storage during chemical disinfection of soft (hydrophilic), rigid gas permeable and hard contact lenses. For use during chemical disinfection only. Not to be used with heat.

This device is manufactured in two variations: clear cap/blue cap and clear base and clear cap/green cap and clear base. The variants follow the same design and have the same intended use. The only difference is the color appearance between the two models. These variations do not affect the safety or effectiveness of the products' intended use. The right cap is labeled with the Letter 'R' to distinguish right and left lenses.

The primary materials which compose the applicants device are M800E Polypropylene produced by Sinopec Shanghai Petrochemical Company Limited Plastics Division which is a translucent raw material and Heliogen Blue K6911D and Heliogen Green K8730 by BASF Corporation used as color additives.

The applicant device of Contact Lens Case consists of 2 parts: case bottom (body) and case caps (covers). The volume of each of the two chambers in the applicant device is 3.8ml and the inner height of both wells is 10mm. The capacity of each well is sufficient for contact lens to be fully immersed under use conditions and can accommodate all lenses currently on the market.

5.0 Intended Use:

The applicant contact lens case is for storage during chemical disinfection of soft (hydrophilic), rigid gas permeable and hard contact lenses. For use during chemical disinfection only. Not to be used with heat.

6.0 Technological Characteristics

	Sacks Holdings, Inc Contact Lens Case	i-Promotions Contact Lens Case (K042578)
Intended Use	Contact Lens Storage and Chemical Disinfection	Contact Lens Storage and Chemical Disinfection
Materials	Similar	Similar
Design	Similar Case bottom with screw on caps The letter "R" embossed on right cap Right and Left cap contrasting colors	Similar Case bottom with hinged on caps The letter "R" embossed on right cap Right and Left cap same colors
Labeling	Similar	Similar

Non-Clinical Performance Data

Sacks Holdings, Inc. Contact Lens Cases have been evaluated in accordance with Part 10993 of the International Standard Organization (ISO). Standard tests administered include:

- ISO 10993-5: 1999 Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity. The test article is considered **non-cytotoxic** under the conditions of the test.
- ISO 10993-10 2002 Biological Evaluation of Medical Devices – Tests of Irritation and Delayed-Type Hypersensitivity. Under the conditions of this study, the Contact Lens Cases were classified as non-irritating.
- ISO 10993-11: 2006 Biological Evaluation of Medical Devices – Tests for Systemic Toxicity. The requirements of the ISO Acute Systemic Injection Test **have been met** by the test article.

Substantial Equivalence

Sacks Holding's contact lens storage case is as safe and effective as the identified predicate device. Sacks Holding's contact lens storage case has the same intended uses / indications for use and similar technological characteristics and principles of operation as the predicate device. Similar to the predicate device, biocompatibility testing demonstrates that the subject

device is safe and effective for the intended use. Thus, Sacks Holding's contact lens storage case is substantially equivalent.

Substantial Equivalence Chart

	Sacks Holdings, Inc.'s Contact Lens Storage Case	**i-Promotions Contact Lens Case (K042578)**
Intended Use/Indications for use	For storage during chemical disinfection of soft (hydrophilic), rigid gas permeable and hard contact lenses. For use during chemical disinfection only. Not to be used with heat.	For storage during chemical disinfection of soft (hydrophilic), rigid gas permeable and hard contact lenses. For use during chemical disinfection only. Not to be used with heat.
Disinfection Type	Chemical; Not heat	Chemical; Not heat
Design	Two adjoining wells with screw top caps into which respective lens are immersed	Two adjoining wells with integral hinged caps into which respective lens are immersed
Materials	M800E Polypropylene (Sinopec Shanghai Petrochemical Company Limited Plastics Division) BASF Corporation Colorants: Heliogen Blue K6911D, BASF Heliogen Green K8730	Dow Chemical Company Low Density Polyethylene (Product #9931) Various Carolina Color Corporation Colorants
Biocompatibility	• ISO 10993-5: In Vitro cytotoxicity • ISO 10993-10: Irritation and delayed-type hypersensitivity • ISO 10993-11: Systemic toxicity	• In Vitro cytotoxicity • Delayed-type hypersensitivity • Eye irritation • Systemic toxicity
Sterilization	Not sold sterile	Not sold sterile

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

Sacks Holdings, Inc.
c/o Mr. Devin Chodorow
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P.O. Box 676211
Rancho Santa Fe, CA 92067

JUL 6 2012

Re: K121030
Contact Lens Storage Case
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LRX
Dated: June 6, 2012
Received: June 7, 2012

Dear Mr. Chodorow:

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,

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

K121030

Indications for Use Statement

510(k) Number (if known): K121030

Device Name: Contact Lens Storage Case

Indications for Use:

For storage during chemical disinfection of soft (hydrophilic), rigid gas permeable and hard contact lenses. For use during chemical disinfection only. Not to be used with heat.

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

Julie Kim, M.D.

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

510(k) Number K121030