K042977

MAY 10 2005

SECTION 5 – 510 (K) SUMMARY

Submitted: October 20, 2004

By: Ivan N. Harlan

Trade Name: LASIK Eyelid Drape

Common Name: Drape, Surgical

Classification Name: Drape, Surgical [per 21 CFR _ 878]

Summary:

This device, made of medical grade polyethylene tape and coated with a pressure sensitive acrylate adhesive, is designed to support LASIK surgery, as well as a variety of other ophthalmic procedures by promoting a clean and dry sterile field. The LASIK Eyelid Drape is intended by design to drape the eyebrow, completely drape the eye or provide complete occlusion of the eyelid. In addition, it can be trimmed to aid in retracting lashes without obstructing the surgical site.

By design, material and intended use, the LASIK Eyelid Drape is substantially equivalent to the BD Visiflex incise Drape (Becton, Dickinson, and Company).

Equivalences and differences between the two devices may be described as follows:

Both the BD Visiflex incise and Odyssey Lasik Eyelid Drapes are designed to promote a clean and dry sterile field and are secured directly to the skin via a pressure sensitive adhesive. Both drapes have peelable liner backings and are indicated for refractive and general ophthalmic office procedures. In addition, both drapes are universally designed for setup on the left or right eye and are indicated for complete or partial coverage of the eye, as well as retraction of the eyelids to reduce the risk of infection.

The material and performance characteristics of the BD Visiflex incise Drape is unknown at this time, however, the Odyssey Lasik Eyelid Drape material is reportedly easy to apply and conformable with good adhesion to skin. The Odyssey product has a pressure sensitive adhesive.

Both the BD Visiflex incise and Odyssey Lasik Eyelid Drapes are supplied sterile, utilizing Gamma Irradiation. The Odyssey Lasik Eyelid Drape is single sterile barrier pouched. The sterile barrier of the BD Visiflex incise Drape is unknown at this time.

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SECTION 6 – DEVICE DESCRIPTION

This drape device with a pressure sensitive adhesive is designed to promote a clean and dry sterile field. It has good adhesion to the skin It is also comfortable, transparent and easy to apply. The device is designed to drape the eyebrow or completely drape the eye. In addition, it can be trimmed to drape and retract the eyelids from the surgical site

Design Specifications	Reference
Lasik Eylid Drape	6-2

Material Specifications

Transparent Polyethylene Medical Tape	6-3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 10 2005

Mr. Ivan Harlan
Director Regulatory Affairs/Quality Assurance
Odyssey Medical, Incorporated
5828 Shelby Oaks Drive
Memphis, Tennessee 38134

Re: K042977
Trade/Device Name: LASIK Eye Drape
Regulation Number: 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: May 2, 2005
Received: May 2, 2005

Dear Mr. Harlan:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042977

Device Name: LASIK Eye Drape

Indications For Use:

Odyssey's L.E.D. provides a sterile adhesive surgical barrier for a variety of ophthalmic procedures, including LASIK. Prepare and drape the patient in the normal ophthalmic fashion. Hold back the eyelashes from the visual field as required. Care should be taken when removing the drape from the adhesive backing not to tear or damage the device. Apply the L.E.D. in the required area to provide proper occlusion and maintain a clean and dry sterile field. The Lasik Eyelid Drape is designed to drape the eyebrow, completely drape the perimeter of the eye or provide complete occlusion of the eyelid. It can also be trimmed to aid in retracting lashes without obstructing the surgical site. While the adhesive holds the drape securely in place, removal is easy and painless for patients. A non-adhesive red tab is located on each side of the drape to aid in removal.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K042977