ODYSSEY - K972523

SEP 9 1997

SECTION 5 - 510(K) SUMMARY

Submitted: August 28, 1997

By: Raymond G. Wallace

Trade Name: Punctal Occluder

Common Name: Punctum Plugs

Classification Name: Punctum Plugs (per 21 CFR § 886)

Summary:

This device, made of medical grade silicone, titanium dioxide as a colorant and utilizing a propritary surface treatment made under current good manufacturing practices, is a small, generally "plug" shaped design. Punctal Occluders are intended for the treatment of "dry eye" conditions through the total occlusion of individual punctal openings.

By material, design and intended use, the Odyssey Punctal Occluder is substantially equivalent to the previous Odyssey Punctal Occluder.

Differences between the two devices may be described as follows:

The old Odyssey plug has a larger "solid" diameter nose, whereas the new plug has a larger overall diameter, but a *smaller* "effective" or "solid" diameter nose to ease required insertion pressure and removal trauma. The new plug is also somewhat shorter to enhance the anchoring of the flange under the fibroelastic punctal ring.

The new plug has been surface enhanced utilizing ion beam technology to reduce the friction and increase the hydrophilicity of the plug for additional ease of insertion and comfort for the wearer. Testing has indicated that the surface treatment does not reduce the biocompatibility of the device.

Alternative methods of punctal occlusion are either permanent or difficult to reverse. In contrast, the submitted method is both functionally safe and fully reversible. Unlike some other methods, this device does not require the breach of intact tissue surfaces nor the risk of damaging said surfaces should reversal become desirable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Raymond A. Wallace
Director, Technical Services
Odyssey Medical, Inc.
1710 Shelby Oaks Dr., Suite 21
Memphis, TN 38134

SEP 9 1997

Re: K972523
Trade Name: Punctal Occluder
Regulatory Class: Unclassified
Product Code: 86 LZU
Dated: July 1, 1997
Received: July 7, 1997

Dear Mr. Wallace:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is 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 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 (Premarket Approval), 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 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 device 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.

This letter will allow you to begin marketing your device as described in your 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 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 device, 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,

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

Enclosure

STATEMENT OF INDICATIONS FOR USE

Punctal Occluders (plugs) are indicated for the treatment of "dry eye" syndrome. "Dry eye being a condition where there is insufficient lubrication in the eye and the conjunctive becomes much less moist than normal. This produces pain and discomfort in the eyes. This may occur in any condition that causes scars of the cornea, such as erythema multiforme, trachoma, or corneal burns;"[1] ...etc. Other patients that may benefit are: cataract patients, patients with arthritis, patients medicated for hypertension, contact wearers of any age, seasonal allergy sufferers, patients who live in dry climates, or spend extended periods in air conditioning, and any others who suffer from dry eye irritation. Treatment is to stop tear outflow via a specific punctum to enhance tear contact time in certain dry eye conditions. It is also reasonable that eye drops of many kinds would be more effective if retained on the surface of the eye, rather than drained into the sinus.

[1] Taber's Cyclopedic Medical Dictionary © 1989

Donna Vochner.
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K972523

Prescription Use ✓
(Per 21 CFR 801.109)