

K 980437

APR 30 1998

February 2, 1998

510(k) SUMMARY

Submitted by:

James Christensen
OASIS Medical, Inc.
514 South Vermont Avenue
Glendora, CA 91741
(626) 914-2891 (Phone)
(626) 914-2285 (Fax)

Device Name:

Common Name: Punctal Plug
Proprietary Name: Silicone Punctal Plug

Device Classification:

Lacrimal system plugs have not been officially classified, but have been historically been regulated through the 510(k) process.

Indication

The Silicone Punctal Plug is intended for use in patients experiencing dry eye symptoms such as redness, burning, reflex tearing, itching or foreign body sensations which can be relieved by blockage of the punctum

Silicone Punctal Plug may be used in the treatment of dry eye syndrome and the dry eye components of various ocular surface diseases such as corneal ulcers, conjunctivitis, pytergium, blepharitis, keratitis, red lid margins, recurrent chalazions, recurrent corneal erosion, filamentary keratitis and other external eye diseases.

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. 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.

Description:

The OASIS Medical Silicone Punctal Plug is designed to be inserted into the punctal opening in order to block tear drainage through the canaliculus. Each Punctal Plug is molded from medical grade silicone and comes premounted on an inserter. The plugs are available in the following sizes:

	GAUGE SIZE	HEAD DIA.	NOSE DIA.	LENGTH
Micro	0.4	0.6 mm	0.6 mm	1.1 mm
Mini	0.5	0.7 mm	0.7 mm	1.3 mm
Petite	0.6	0.9 mm	0.9 mm	1.4 mm
Small	0.7	0.9 mm	1.0 mm	1.8 mm
Medium	0.8	0.9 mm	1.4 mm	2.0 mm

Substantial Equivalence Comparison:

The OASIS Medical Silicone Punctal Plug is substantially equivalent to the OASIS Medical Silicone Punctal Plug (K945906). The OASIS Medical Silicone Punctal Plug is identical to the predicate device except for its physical design and a modified inserter.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 1998

Mr. James Christensen
Oasis Medical, Inc.
514 S. Vermont Avenue
Glendora, CA 91741

Re: K980437
Trade Name: Soft Plug® Silicone Punctal Plug
Regulatory Class: Unclassified
Product Code: 86 LZU
Dated: February 2, 1998
Received: February 4, 1998

Dear Mr. Christensen:

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.

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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

510(k) Number (if known): K 980437

Device Name: Silicone Punctal Plug

Indications for Use:

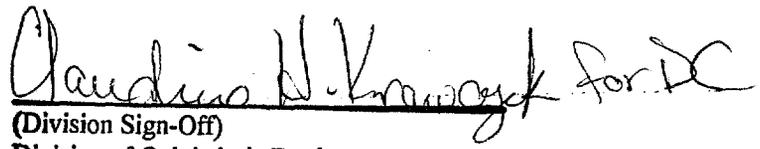
The OASIS® Medical Silicone Punctal Plug is intended for use in patients experiencing dry eye symptoms such as redness, burning, reflex tearing, itching or foreign body sensations which can be relieved by blockage of the punctum

Silicone Punctal Plug may be used in the treatment of dry eye syndrome and the dry eye components of various ocular surface diseases such as corneal ulcers, conjunctivitis, pytergium, blepharitis, keratitis, red lid margins, recurrent chalazions, recurrent corneal erosion, filamentary keratitis and other external eye diseases.

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(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 Ophthalmic Devices

510(k) Number K980437

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____