K030300

MAY - 9 2003

Summary of Safety and Effectiveness (Updated)

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a Summary of Safety and Effectiveness for the proposed Lacrimedics Dissolvable Opaque Herrick Lacrimal Plug® device.

Manufacturer: Lacrimedics

Contact Person: Jerry Henderson
310 Prune Alley
Eastsound, WA 98245-1209

Device Name:

Trade Name: Dissolvable Opaque Herrick Lacrimal Plug®

Common Name: Intracanalicular Plug/Punctum Plug

Proprietary name: TBD

Classification: LZU; Ophthalmic

Date Prepared: May 1, 2003

Device Description: The Lacrimedics Dissolvable Opaque Herrick Lacrimal Plug® provides temporary occlusion of the tear drainage system. The plug is supplied in various sizes ranging from 0.2 mm to 0.5mm in diameter. The length is approximately 1.75 mm. The dissolvable (suture material) plug is composed of any one of the following: (1) a copolymer of L-lactide and ε -caprolactone (PCL); (2) polydioxanone (PDO); (3) copolymers of glycolic acid and trimethylene carbonate.

The proposed device is supplied as a single use component for use in treatment of dry eye syndrome. The device is supplied sterile and is intended for SINGLE USE ONLY.

Intended Use: The Lacrimedics Dissolvable Opaque Herrick Lacrimal Plug® is intended to block the canaliculus for the relief of dry eye syndrome.

Indications: Dissolvable Opaque Herrick Lacrimal Plug® may be used:

- As a diagnostic aid to determine the potential effectiveness of Occlusion Therapy with non-dissolvable plugs.
- To temporarily enhance the efficacy of topical medications or ocular lubricants
- After ocular surgery to prevent complications due to dry eyes.
- To evaluate treatment of ocular dryness secondary to contact lens use
- In the treatment of Dry Eye Syndrome and the dry eye components of varying Ocular Surface Diseases.

Comparison of Technological Characteristics: The proposed device, the Dissolvable Opaque Herrick Lacrimal Plug®, comprises the same or similar material as the predicate devices. Manufacture of this device, and QC testing, is in substantial compliance with current FDA guidelines and 21 CFR 820 regulations.

end

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2003

Lacrimedics
c/o Jerry Henderson
RA / QA Specialist
P.O. Box 1209
310 Prune Alley
Eastsound, WA 98245-1209

Re: K030300
Trade/Device Name: Dissolvable OPAQUE Herrick Lacrimal Plug®
Regulatory Class: Unclassified
Product Code: LZU
Dated: April 10, 2003
Received: April 17, 2003

Dear Mr. Henderson:

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 (301) 594-4613. 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/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

510(k) Number (if known): K030300

K030300

Device Name: Dissolvable Opaque Herrick Lacrimal Plug≤

Indications for Use:

Dissolvable Opaque Herrick Lacrimal Plugs may be used:

- ξ As a diagnostic aid to determine the potential effectiveness of Occlusion Therapy with non-dissolvable plugs.
- ξ To temporarily enhance the efficacy of topical medications or ocular lubricants
- ξ After ocular surgery to prevent complications due to dry eyes.
- ξ To evaluate treatment of ocular dryness secondary to contact lens use
- ξ In the treatment of Dry Eye Syndrome and the dry eye components of varying Ocular Surface Diseases.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochner

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

510(k) Number K030300

(Optional Format 3-10-98)