Section 5

JUN 0 3 2014

K140026

510(k) Summary – VisiPlug®ST for the Lacrimal Efficiency Test

Submitted by:	Lacrimedics, Inc. PO Box 1209 434 Prune Alley Eastsound, WA 98245-1209
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Date Summary Prepared:	June 2, 2014
Device Trade Name:	VisiPlug®ST for the Lacrimal Efficiency Test™
Device Common Name:	Punctum plug
Classification Name:	Punctum Plug
Product Code:	LZU
Primary Predicate Devices:	Collagen Plugs for the Lacrimal Efficiency Test 510(k): K895342
Device Description:	The proposed device is an ophthalmic device commonly referred to as a punctum plug. It is designed to be placed by a practitioner into the horizontal canaliculus to restrict the natural lubricating tears from being pumped off the eye. VisiPlug®ST provides temporary occlusion of the tear drainage system. The device may be used as a diagnostic aid to determine the potential effectiveness of long-term occlusion, to temporarily enhance the efficacy of topical medications or ocular lubricants, after surgery to prevent complications due to dry eyes, to evaluate treatment of ocular dryness secondary to contact lens use, and to evaluate the dry eye component of ocular surface diseases (OSD). VisiPlug®ST plugs are cylindrical in shape, approximately 1.75-2.00mm in length, and available in three sizes: 0.3mm, 0.4mm and 0.5mm. Each plug is cut from a monofilament strand of Glycoprene® MG23, a synthetic surgical grade polymer composed of poly(glycolide-co-trimethylene carbonate-co-caprolactone).

	The monofilament is dyed with an approved color additive, Green D & C 6 (CAS# 128-80-3; 0.1% by weight). Titanium dioxide is added to the polymer to make the plugs opaque, providing a satisfactory means with which to determine the plug's presence or absence following insertion by a practitioner.
Indications for Use:	VisiPlug®ST provide temporary occlusion of the tear drainage system. VisiPlug®ST may be used as a diagnostic aid to determine the potential effectiveness of long-term occlusion, to temporarily enhance the efficacy of topical medication or ocular lubricants, after surgery to prevent complications due to dry eyes, to evaluate treatment of ocular dryness secondary to contact lens use, and to evaluate the dry eye component of ocular surface diseases (OSD).
Differences:	The VisiPlug®ST Indications for Use do not name the specific ocular surface diseases; the listed conditions in the Predicate Device Indications for Use are representative only, not all inclusive. VisiPlug$_{ST}$ plugs are for short-term (temporary) occlusion.
Technological Characteristics:	The proposed device has the same design as the Primary Predicate Device. Reference Devices: Maxon, Sterile Synthetic Absorbable Sutures 510(k): K990951 CaproSyn Suture 510(k): K032586
Differences:	The Primary Predicate Device is comprised of animal tissue. The proposed device is comprised of a copolymer similar to the Referenced Predicate Devices which have been approved for soft tissue approximation and ophthalmic surgeries.
Nonclinical Tests:	Performance Data testing was conducted to compare the strength and mass loss degradation rates of Glycoprene® MG23 to that of gut suture (material used for the Primary Predicate Device). The material used for the proposed device, Glycoprene® MG23, has a similar strength retention and mass loss profile as that of the Primary Predicate Device. Glycoprene® MG23 has a 40% strength retention rate at 4-5 days

Nonclinical Tests: (continued)	compared to 40% strength retention at 3 days for gut suture. Mass loss profiles at 30 days are 46% and 45% respectively. Results of biocompatibility studies for VisiPlug®ST for the Lacrimal Efficiency Test indicate the proposed device is safe.
Conclusions:	The proposed device has the same design, performance and safety profile as that of the Primary Predicate Device and is therefore substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 3, 2014

Lacrimedics, Inc.
Ms. Rebecca Dutton
Director of Operations
434 Prune Alley
Eastsound, WA 98245

Re: K140026
Trade/Device Name: VisiPlug™ST for the Lacrimal Efficiency Test (Models 1813, 1814, and 1815)
Regulation Number: Preamendment
Regulation Name: Preamendment
Regulatory Class: Unclassified
Product Code: LZU
Dated: April 21, 2014
Received: April 24, 2014

Dear Ms. Dutton:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K140026

Device Name: VisiPlug®ST

Indications for Use:

VisiPlug®ST provide temporary occlusion of the tear drainage system. VisiPlug®ST may be used as:

- a diagnostic aid to determine the potential effectiveness of long-term occlusion,
- to temporarily enhance the efficacy of topical medications or ocular lubricants,
- after surgery to prevent complications due to dry eyes,
- to evaluate treatment of ocular dryness secondary to contact lens use,
- and to evaluate the dry eye component of ocular surface diseases (OSD).

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

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Claudine H. Krawczyk -S
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