DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 28, 2015

Riverpoint Medical
Mr. Edwin Anderson
Director of Quality and Regulatory
825 NE 25th Avenue
Portland, OR 97232

Re: K150288
Trade/Device Name: PDO Absorbable Canalicular Plug
Regulation Number: 21 CFR Unclassified
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: LZU
Dated: July 17, 2015
Received: July 20, 2015

Dear Mr. Anderson:

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" (21 CFR 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,

Kesia Y. Alexander -A

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150288/S002

Device Name
PDO Absorbable Canalicular Plug

Indications for Use *(Describe)*
The Riverpoint Medical Absorbable Canalicular Plugs are intended to temporarily block tear drainage by the obstruction of the canaliculus in the lacrimal drainage system. The Absorbable Canalicular Plugs are used for the temporary treatment of dry eye syndrome, and the dry eye components of various ocular surface diseases including contact lens intolerance secondary to dry eye. The Absorbable Canalicular Plugs can be used in the treatment of dry eye following ocular surgery or to enhance the efficacy of topical medicines and/or ocular lubricants. The Riverpoint Medical Absorbable Canalicular Plugs may also be used to determine the potential effectiveness of a nonabsorbable punctal occlusion device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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RIVERPOINT MEDICAL

510(k) SUMMARY

Riverpoint Medical 's PDO Absorbable Canalicular Plug

Submitter Information

Submitter's Name:	Riverpoint Medical
Address:	825 NE 25th Ave. Portland, OR 97232
Phone Number:	(503) 517-8001 or 866 445-4923
Fax Number:	(503) 517-8002
Registration Number:	3006981798
Contact Person:	Edwin Anderson (503) 517-8001
Date of Preparation:	February 3, 2015

Device Name

Trade Name:	PDO Absorbable Canalicular Plug
Common or Usual Names:	Punctum/Punctal Plug, Intracanalicular Plug, Canalicular Plug
Classification Name:	Plug, Punctal

Device Classification

FDA Class:	Unclassified
Product Classification:	Unclassified
Classification Code:	LZU
Review Panel	Ophthalmic
Premarket Review	Office of Device Evaluation Division of Ophthalmic and Ear, Nose and Throat Devices Intraocular and Corneal Implants Devices Branch

Predicate Devices

K140711 - Comfortear® Lacrisolve™ Absorbable Punctum Plug –Paragon BioTeck, Inc.

Device Description:

The Riverpoint Medical PDO Absorbable Canalicular Plug is a monofilament synthetic absorbable device prepared from poly(p-dioxanone). PDO Absorbable Canalicular Plugs are available undyed or violet. When dyed, only FDA-approved color additives such as D&C Violet No. 2 are used. PDO Absorbable Canalicular Plugs are used to temporarily block tear drainage by the occlusion of the lacrimal canaliculi for approximately 180 days.

RIVERPOINT MEDICAL

Intended Use / Indications for Use

The Riverpoint Medical Absorbable Canalicular Plugs are intended to temporarily block tear drainage by the obstruction of the canaliculus in the lacrimal drainage system. The Absorbable Canalicular Plugs are used for the temporary treatment of dry eye syndrome, and the dry eye components of various ocular surface diseases including contact lens intolerance secondary to dry eye. The Absorbable Canalicular Plugs can be used in the treatment of dry eye following ocular surgery or to enhance the efficacy of topical medicines and/or ocular lubricants. The Riverpoint Medical Absorbable Canalicular Plugs may also be used to determine the potential effectiveness of a non-absorbable punctal occlusion device.

Technological Characteristics

The Riverpoint Medical Absorbable Canalicular Plugs are provided sterile, sterilized via ethylene oxide, for single use with two plugs per package. Plugs are available in 0.2mm, 0.3mm, 0.4mm and 0.5mm diameters.

Substantial Equivalence

The Riverpoint Medical Absorbable Canalicular Plug is as safe and effective as the Comfortear® Lacrisolve™ Absorbable Punctum Plug. The Riverpoint Medical Absorbable Canalicular Plugs have the same intended use and similar indications for use, principles of operation, and technical characteristics, including implant duration, material, shape, color additives, diameter availability, sterilization method, and insertion or removal method as the predicate device, see the following table. The Riverpoint Medical Absorbable Canalicular Plugs minor technological differences as compared to the predicate device do not raise new issues of safety or effectiveness. Performance, biocompatibility and sterility testing demonstrated that the Riverpoint Medical product is as safe and effective as the predicate device and additional testing is performed on each lot of product to verify that requirements have been met prior to release. The Riverpoint Medical Absorbable Canalicular Plugs are substantially equivalent to the predicate device.

Device Technological Characteristic	**Riverpoint Medical PDO Absorbable Canalicular Plug**	**Paragon Bioteck, Inc.,Comfortear® Lacrisolve™ Absorbable Punctum Plugs (K140711)**
Intended Use	The Riverpoint Medical Absorbable Canalicular Plugs are intended to temporarily block tear drainage by the obstruction of the canaliculus in the lacrimal drainage system. The Absorbable Canalicular Plugs are used for the temporary treatment of dry eye syndrome, and the dry eye components of various ocular surface diseases including contact lens intolerance secondary to dry eye. The Absorbable Canalicular Plugs can be used in the treatment of dry eye following ocular surgery or to enhance the efficacy of topical medicines and/or ocular lubricants. The Riverpoint Medical Absorbable Canalicular Plugs may also be used to determine the potential effectiveness of a non-absorbable punctal occlusion	The Comfortear® Lacrisolve™ Absorbable Punctum Plugs are intended to temporarily block tear drainage by the occlusion of the canaliculus in order to: • Determine the potential effectiveness of permanent occlusion, • Temporarily treat dry eye syndrome, and the dry eye components of various ocular surface diseases, • Temporarily enhance the efficacy of topical medications or ocular lubricants, • Temporarily treat contact lens intolerance secondary to dry eye, and • Temporarily treat dry eye after ocular surgery.

Device Technological Characteristic	Riverpoint Medical PDO Absorbable Canalicular Plug	Paragon Bioteck, Inc.,Comfortear® Lacrisolve™ Absorbable Punctum Plugs (K140711)
	device.	
Intracanalicular Punctum Plug	Yes	Yes
Intended Duration	Approximately 180 Days	Approximately 180 Days
Material	Polydioxanone (PDO)	Polydioxanone (PDO)
Color Additive	D&C Violet No. 2	D&C Violet No. 2
Shape	Cylindrical	Cylindrical
Diameter Availability	0.2mm-0.5mm	0.2mm-0.5mm
Length	2.0mm	1.75mm
Packaging	Foil Pouch	Tyvek/Poly Pouch
Biocompatibility	Biocompatible per ISO10993	Biocompatible per ISO10993
Sterilization	EtO Sterilization	EtO Sterilization
Insertion Methods	Manual with Forceps	Manual with Forceps
Removal Methods	Irrigation, Probe, or Dissolution	Irrigation, Probe, or Dissolution

Performance Data

Non-clinical performance testing for the Riverpoint Medical Absorbable Canalicular Plugs included sterilization validation per ISO11135-1:2007 - Sterilization of Health Care Products Ethylene Oxide Part 1: Requirements for the Development, Validation, and Routine Control of a Sterilization Process for medical devices, biocompatibility testing per ISO10993-1:2009 - Biological Evaluation of Medical Devices, stability testing on the product and packaging per ISO 11607-1:2006 - Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems, and a simulated use Usability Validation performed per EN62366: 2008- Medical devices - Application of usability engineering to medical devices. All acceptance criteria were met, and the Riverpoint Medical Absorbable Canalicular Plug performed as intended.

Conclusion

Based on the information provided within this 510(k) submission, Riverpoint Medical concludes that the proposed Absorbable Canalicular Plugs do not raise significant questions of safety or effectiveness and is substantially equivalent to the predicate device.