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510(k) Summary

JUL -8 2010

Submitter Information

Submitter's Name:	Riverpoint Medical
Address:	825 NE 25th Ave. Portland, OR 97232
Phone Number:	(503) 517-8001 or 866 445-4923
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Registration Number:	3006981798
Contact Person:	Douglas Rowley (503) 517-8001
Date of Preparation:	February 03, 2010

Device Names

Trade Names:

PDO:	PDM
PGCL:	Mono Q
PGA:	Vilet
Fast Absorbing PGA:	Vilet Quick

Common Names: Absorbable Surgical Sutures: PDO, PGA, PGCL

Classification Names: All: General and Plastic Surgery Devices

Device Classification

FDA Class: 2 (All varieties listed)

Product Classification:

1.	Polydioxanone (PDO):	878.4840, Absorbable polydioxanone surgical suture
2.	Polyglycolic Acid (PGA):	878.4493, Absorbable poly(glycolide/l-lactide) surgical suture
3.	Fast Absorbing Polyglycolic Acid (PGA):	878.4493, Absorbable poly(glycolide/l-lactide) surgical suture
4.	Poly(glycolide-co-caprolactone)(PGCL):	878.4493, Absorbable poly(glycolide/l-lactide) surgical suture

Codes:

1.	Polydioxanone (PDO):	NEW
2.	Polyglycolic Acid (PGA):	GAM
3.	Fast Absorbing PGA:	GAM
4.	Poly(glycolide-co-caprolactone)(PGCL):	GAM

Classification Panel: All: Class II (special controls); General and Plastic Surgery

Predicate Devices (applicable 510(k) number listed):

1.	PDO:	K061037
2.	PGA:	K972566
3.	Fast Absorbing PGA:	K023710
4.	PGCL:	K960653

Special Controls

FDA Guidance "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA" was followed during the preparation of this submission.

Device Description

Riverpoint Medical Absorbable surgical sutures are medical devices used to secure tissues together or create wound closures during a surgical procedure or after an injury. They are composed of the applicable suture material and a standard medical grade suture needle as applicable (sutures can be provided without needles as well).

Available Suture sizes will be standard according to USP 32 requirements (12/0 through 7, depending on suture type).

Intended Use

PDO: PDO surgical suture is indicated for use in general soft tissue approximation and/or ligation, including use in pediatric cardiovascular tissue where growth is expected to occur and ophthalmic surgery other than contact with cornea and/or sclera. PDO Suture is not intended for use in adult cardiovascular tissue, microsurgery or neural tissue.

PGA: PGA surgical suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular or neural tissue.

Fast Absorbing PGA (Trade Name: Vilet Quick): Vilet Quick surgical suture is indicated for use in general soft tissue approximation, including use in ophthalmic procedures, where only short-term wound support is required. Vilet Quick is not intended for use in cardiovascular or neurological procedures.

PGCL: PGCL surgical suture is indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological procedures.

Safety and Effectiveness

Each variety of Riverpoint Medical absorbable sutures has been designed and manufactured to be substantially equivalent to the predicate devices listed for safety and effectiveness. Materials used were selected based on known biocompatibility (per ISO 10993) and established histories of use in the medical device industry for implantable devices, and are identical or substantially equivalent to the materials used in the predicate devices listed. Biocompatibility testing performed on each variety of absorbable sutures within this submission includes the following: Cytotoxicity, Sensitization, Intracutaneous Reactivity, Systemic Toxicity, Genotoxicity - Bacterial Reverse Mutation and Chromosomal Aberration, Bone Marrow Micronucleus, Subchronic Toxicity (4-week, following subcutaneous implantation), Muscle Implantation (12-week).

Riverpoint Medical absorbable sutures have been designed to meet the requirements for diameter, tensile strength, and needle attachment strength as specified within USP 32. Testing is performed on each lot of product to verify that USP requirements have been met prior to release.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Riverpoint Medical
% Mr. Doug Rowley
RA/QA Manager
825 NE 25th Avenue
Portland, Oregon 97232

JUL - 8 2010

Re: K100461
Trade/Device Name: Polyglycolic Acid (PGA) Absorbable Surgical Suture, PGA Absorbable Surgical Suture (Fast Absorbing), Poly(glycolide co-caprolactone) PGCL) Absorbable Surgical Suture, Polydioxanone (PDO) Absorbable Suture
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly(glycolide/L-lactide) surgical suture
Regulatory Class: II
Product Code: GAM, NEW
Dated: June 7, 2010
Received: July 2, 2010

Dear Mr. Rowley:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: Unknown at this time

Device Name: Polyglycolic Acid (PGA) Absorbable Surgical Suture

Trade Name: Vilet

Indications for Use:

PGA surgical suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular or neural tissue. PGA suture is provided sterile as a single use device.

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 CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100461

Indications for Use Statement

510(k) Number: Unknown at this time

Device Name: PGA Absorbable Surgical Suture (Fast Absorbing)

Trade Name: Vilet Quick

Indications for Use:

Vilet Quick surgical suture is indicated for use in general soft tissue approximation, including use in ophthalmic procedures, where only short-term wound support is required. Vilet Quick is not intended for use in cardiovascular or neurological procedures.
Vilet Quick suture is provided sterile as a single use device.

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 CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K190461

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Indications for Use Statement

510(k) Number: Unknown at this time

Device Name: Poly(glycolide co-caprolactone) (PGCL) Absorbable Surgical Suture

Trade Name: Mono Q

Indications for Use:

PGCL surgical suture is indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological procedures.
PGCL suture is provided sterile as a single use device.

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 CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K100461

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Indications for Use Statement

510(k) Number: Unknown at this time

Device Name: Polydioxanone (PDO) Absorbable Surgical Suture

Trade Name: PDM

Indications for Use:

PDO surgical suture is indicated for use in general soft tissue approximation and/or ligation, including use in pediatric cardiovascular tissue where growth is expected to occur and ophthalmic surgery (other than contact with cornea and/or sclera). PDO Suture is not intended for use in adult cardiovascular tissue, microsurgery or neural tissue.
PDO suture is provided sterile as a single use device.

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

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510(k) Number K100461