JUL 18 2014

510(k) Summary

Date Prepared:	Jul 17, 2014	
Company:	Surgical Specialties Corporation 100 Dennis Dr. Reading, PA 19606	
Contact:	Paul Amudala Regulatory Affairs Specialist	
	Phone: Fax: Email:	610-404-3376 610-404-3924 pamudala@surgicalspecialties.com
Device trade name:	PolySyn™ (PGA) Surgical Suture	
Device Common Name:	Absorbable Polyglycolic Acid Surgical Suture	
Device classification:	Suture, Absorbable, Synthetic, Polyglycolic Acid Product code, GAM 21 CFR 878.4493 Class II	
Legally marketed device to which the device is substantially equivalent:	K965162: K022269	PolySyn™ Surgical Suture (primary) Coated VICRYL™ (Polyglactin) Suture (reference)
Description of the device:	PGA Sutures are supplied as braided or monofilament, dyed (violet) or undyed and coated or uncoated. The pigment for the violet is D&C Violet #2. Where applicable, the coating is a copolymer of polycarpolactone and calcium stearate. The PGA Suture is available in Size 2 through Size 10-0.	
Indications for Use:	PolySyn™ (Polyglycolic Acid (PGA)) Suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in Cardiovascular and Neurological procedures.	
Substantial Equivalence:	The proposed additional diameter sizes, USP Size 7-0 through 10-0, of the PolySyn™ suture product line have the same material (K965162), design, intended use and technological characteristics as the predicate device. The only difference between the proposed and predicate (K965162) device is the suture diameter.	

Performance tests:	Non-clinical laboratory performance testing was conducted to confirm that the PolySyn™ suture conforms to the USP monograph for absorbable sutures (as applicable). This testing was performed in accordance with FDA's Class II Special Controls Guidance Document: Surgical Sutures, Issued June 3, 2003. Additional performance testing was conducted in order to demonstrate substantial equivalence to the predicate device including *in vitro* post-hydrolysis tensile testing. The results of this testing demonstrates that the PolySyn™ suture is substantially equivalent to the predicate devices.

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

July 18, 2014

Surgical Specialties Corporation
Mr. Paul Amudala
Regulatory Affairs Specialist
100 Dennis Drive
Reading, Pennsylvania 19606

Re: K141625
Trade/Device Name: POLYSYN™ (Polyglycolic Acid) Surgical Suture
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly(glycolide/L-lactide) surgical suture
Regulatory Class: Class II
Product Code: GAM
Dated: June 18, 2014
Received: June 19, 2014

Dear Mr. Amudala:

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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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 on last page.

510(k) Number *(if known)*
K141625

Device Name
POLYSYN™ (Polyglycolic Acid) Surgical Suture

Indications for Use *(Describe)*
POLYSYN™ Polyglycolic Acid (PGA) Suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in Cardiovascular and Neurological procedures.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Peter L. Hudson -S
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