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

November 23, 2016

Y. Jacobs Medical, Inc.
c/o Ms. Meredith May, M.S., RAC
Empirical Consulting
4628 Northpark Drive
Colorado Spring, Colorado 80918

Re: K160705
Trade/Device Name: Y Jacobs Young's Synthetic Absorbable Surgical Fixation Suture
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable polydioxanone surgical suture
Regulatory Class: Class II
Product Code: NEW
Dated: October 24, 2016
Received: October 26, 2016

Dear Ms. May:

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 below.

510(k) Number *(if known)*
K160705

Device Name
Y. JACOBS YOUNG'S THREAD

Indications for Use *(Describe)*
The Y. JACOBS YOUNG'S THREAD is intended for use in soft tissue approximation where use of an absorbable suture is appropriate.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Y.JACOBS YOUNG'S THREAD
Traditional 510(k)

Y. JACOBS MEDICAL™

Submitter's Name:	Y. JACOBS MEDICAL Inc.
Submitter's Address:	(Nonhyeon-dong) 6F Sangkyung Bldg. 669 Seolleung-ro, Gangnam-gu, Seoul, Korea
Submitter's Telephone:	+82 2-546-0715
Contact Person:	Meredith L. May MS, RAC Empirical Consulting LLC 719.337.7579
Date Summary was Prepared:	10-Mar-2016
Trade or Proprietary Name:	**Y. JACOBS YOUNG'S THREAD**
Common or Usual Name:	Absorbable polydioxanone surgical suture
Classification:	Class II per 21 CFR §878.4840
Product Code:	NEW
Classification Panel:	Division of General and Plastic Surgery.

Description of the Device Subject to Premarket Notification

Y. JACOBS YOUNG'S THREAD synthetic absorbable PDO suture is made of polydioxanone. The pigment for the violet dye is D&C Violet No.2. It degrades and dissolves over time in tissue. Each dyed (violet) suture has uni-directional barbs along the axis of the suture monofilament without needle attachment. The Y. JACOBS YOUNG'S THREAD Synthetic Absorbable PDO suture approximates tissues without the need to tie surgical knots, because of the presence of barbs on the suture surface which imbed in the tissues after precise placement by the surgeon. Y. JACOBS YOUNG'S THREAD consists of absorbable polydioxanone (PDO) suture. Y. JACOBS YOUNG'S THREAD consists of:

- absorbable polydioxanone (PDO) suture
- absorbable PLGA cone with each suture
- disposable polycarbonate hub which has no patient contact

The environment for use of this device is in a medical professional facility, such as a hospital, clinic or specialty treatment center**.**

Indications for Use

The Y. JACOBS YOUNG'S THREAD is intended for use in soft tissue approximation where use of an absorbable suture is appropriate.

Technological Characteristics

Y. JACOBS YOUNG'S THREAD is a Synthetic Absorbable Monofilament made from the following materials:

- Suture: Absorbable PDO with D&C Violet No.2
- Cone: PLGA (82% L-Lactide, 18% Glycolide)
- HUB: Polycarbonate

Y.JACOBS YOUNG'S THREAD
Traditional 510(k) .

Y. JACOBS MEDICAL™

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not affect substantial equivalence. Specifically, the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of manufacture

Table 5-1 Primary Predicate Device

510k Number	Trade or Proprietary or Model Name	Manufacturer
K080985	Quill™ Self-Retaining System (SRS)	Surgical Specialties Corp.

Table 5-2 Additional Predicate Device

510k Number	Trade or Proprietary or Model Name	Manufacturer
K130191	MINT™	Hansbiomed Corp.
K031216	MonoPlus Poly-p-dioxanone absorbable suture	Aesculap, Inc.
K123877	Quill™ PDO Knotless-Tissue Closure Device, Variable Loop	Angiotech

Performance Data
The data presented in this 510(k) encompasses biocompatibility, sterilization, shelf-life, and characterization testing of the suture design.

Summary of Substantial Equivalence
Based on the comparison, as well as the information and data provided in the submission we have demonstrated that the Y. JACOBS YOUNG'S THREAD has been shown to be as substantially equivalent for the proposed Intended and Indications for Use as the legally marketed predicate devices. Therefore, we conclude that the proposed Y. JACOBS YOUNG'S THREAD suture is substantially equivalent to those predicate devices.

Conclusion
The Y. JACOBS YOUNG'S THREAD has the same intended use, material composition (PDO and dye) as the Quill™ Self-Retaining System (SRS) (K080985) and the MINT™ (K130191), MonoPlus Poly-p-dioxanone absorbable suture (K031216), Quill™ PDO Knotless-Tissue Closure Device, Variable Loop (K123877). In addition, K080985 and K130191, K031216 and K123877 are similar design with respect to the barbs and knot or its alternatives for fixation to tissue as the predicates.

Therefore, the Y. JACOBS YOUNG'S THREAD is substantially equivalent to Quill™ Self-Retaining System (SRS) comprised of PDO (K080985) and MINT™ (K130191), MonoPlus Poly-p-dioxanone absorbable suture (K031216), Quill™ PDO Knotless-Tissue Closure Device, Variable Loop (K123877).