July 20, 2021

Y. Jacobs Medical, Inc.
% Meredith May
Vice-President Empirical Consulting
Qserve Group US Inc.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K143413
Trade/Device Name: Y. JACOBS YOUNG'S THREAD
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable polydioxanone surgical suture
Regulatory Class: Class II
Product Code: NEW

Dear Meredith May:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated September 11, 2015. Specifically, FDA is updating this SE Letter as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Cindy Chowdhury, OHT4: Office of Surgical and Infection Control Devices, 240-402-6647, Cindy.Chowdhury@fda.hhs.gov.

Sincerely,

Cindy Chowdhury -S

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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

September 11, 2015

Y. Jacobs Medical, Incorporated
% Ms. Meredith May MS, RAC, Vice-President Empirical Consulting
Qserve Group US Incorporated
4628 Northpark DriveCharleston, New Hampshire 03603

Re: K143413
Trade/Device Name: Y. JACOBS YOUNG'S THREAD
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable polydioxanone surgical suture
Regulatory Class: Class II
Product Code: NEW
Dated: September 1, 2015
Received: September 2, 2015

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,

Binita S. Ashar -S

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)*
K143413

Device Name
Y. JACOBS YOUNGS 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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:	25-Nov-14
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.

The Y. JACOBS YOUNG'S THREAD will be available in single use packages, sterile after ethylene oxide (EO) gas sterilization. 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

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 w here 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

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.
K120827	Quill™ PDO Knotless Tissue-Closure Device (Polydioxanone)	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 provided in the SE Comparison Table in Section 12.5, supported by data found in Sections 11, 14, 15 and 18, 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. The following performance tests were conducted to determine substantial equivalence: tensile strength, strength retention (biodegradability), straight-pull, barb holding force, degradation profile, biocompatibility, and LAL (endotoxin).

Conclusion
The Y. JACOBS YOUNG'S THREAD has the same *Intended Use* for soft tissue approximation as all the predicate sutures.

The Y. JACOBS YOUNG'S THREAD has the same material composition (PDO and dye) as the Quill™ Self-Retaining System (SRS) (K080985) and the MINT™ (K130191) and similar design with respect to the barbs for fixating to tissue as all 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).