



October 11, 2024

Peters Surgical
Vikram Verma
Regulatory Consultant for Peters Surgical
Immeuble AURELIUM, 1 course de l'île Seguin
Boulogne-Billancourt, Hauts-De-Seine 92100
France

Re: K233265

Trade/Device Name: Optime® R
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly(glycolide/l-lactide) surgical suture
Regulatory Class: Class II
Product Code: GAM
Dated: September 12, 2024
Received: September 13, 2024

Dear Vikram Verma:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory->

[assistance/contact-us-division-industry-and-consumer-education-dice](#)) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tek N. Lamichhane - S
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Tek N. Lamichhane, Ph.D.
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Enclosure

Indications for Use

510(k) Number (if known)
K233265

Device Name
OPTIME® R

Indications for Use (Describe)

OPTIME® R sutures are intended for use in general soft tissue approximation including ophthalmic procedures, but not in cardiovascular or 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)

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.

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Abbreviated 510(k) Summary- K233265

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of OPTIME®R Device.

1. Applicant:

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3. Regulatory Correspondent/ 510(k) Submission Contact

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4. Date Prepared: October 11, 2024

5. Device Information:

Device Trade Name	Common Name	Regulatory Classification	Device Class	Product Code	Panel	Predicate Device
OPTIME®R	Absorbable Surgical Suture, coated Polyglycolic Acid braid with fast resorption	Absorbable Poly(glycolide/l-lactide) Surgical Suture (21 CFR 878.4493)	II	GAM	General and Plastic Surgery	Safil Quick Aesculap K031286

6. Device Description:

OPTIME®R sutures are intended to be used in suturing in open or laparoscopic surgery.

These sutures are available with a disposable needle attachment.

OPTIME®R is a sterile, multiple-stranded (multifilament), synthetic bioabsorbable thread made from a polymerization of polyglycolic acid (PGA) used in suturing when short-term support and rapid strength loss are needed. To perform suturing on soft tissue wounds involves a series of precise steps. The surgeon grasps the needle, pushes it through tissue, pulls it through and repeats for continuous suturing. Further, knots are tied, excess thread is cut, and used needles are single use and safely disposed in accordance with hospital procedure.

7. Indication for Use:

OPTIME®R sutures are intended for use in general soft tissue approximation including ophthalmic procedures, but not in cardiovascular or neurological procedures.

8. Comparison of Technological Characteristics

The Absorbable Suture OPTIME®R device is substantially equivalent to the predicate device listed above table in term of intended use, design, performance and principle of operation when compared to the technological characteristics and is available in similar configurations and materials. Below the comparison table specifies substantial equivalence comparison between proposed device and predicate device. Any differences between OPTIME®R suture and it's predicate device are insignificant and do not raise any issues regarding safety or performance of OPTIME®R Surgical Suture.

OPTIME® R Comparison of technological characteristics to the predicate device:

Comparative Characteristics	Proposed Device : OPTIME® R	Predicate Device: Safil Quick
510(k) Number	K233265	K031286
Classification	General and Plastic Surgery	General and Plastic Surgery
Device Description	OPTIME® R device is an absorbable synthetic surgical implantable suture. The sutures are undyed, sterile comprised of rapidly resorbing coated polyglycolic acid braid.	Safil Quick device is an absorbable, flexible multifilament suture thread which is supplied dyed, undyed, and sterile. It is composed of a synthetic polyglycolic acid polymer, and it is indicated for soft tissue approximation where only short-term wound support is required.
Product Code	GAM	GAM
Indication for Use	OPTIME® R synthetic absorbable surgical sutures are indicated for use in general soft tissue approximation, including in ophthalmic procedures, but not in cardiovascular or neurological procedures.	Safil Quick sutures are indicated for use in general soft tissue approximation, including ophthalmic procedures, but not in cardiovascular or neurological procedures.
Regulation	21 CFR 878.4493	21 CFR 878.4493
Regulatory Class	Class II	Class II
Single Use	Yes	Yes
Principle Device Components (Sterile, Disposable and Single Use)	Thread with attached needle	Thread with attached needle
Type of Device (Material Used)	Absorbable PGA (Polyglycolic acids) suture	Absorbable PGA (Polyglycolic acids) suture
Biocompatibility Requirements	ISO 10993	ISO 10993
Sterilization methods	Gamma	Gamma
Technical Features/Design		
Thread material	PGA - Polyglycolic Acid	PGA - Polyglycolic Acid
Thread coating	Coating composed of a mixture of polycaprolactone and calcium stearate ($\leq 5\%$)	Polyglyconate coating
Thread size	USP 6/0 to USP 1	USP 7/0 to USP 2
Thread length	45 cm to 90 cm	30 cm to 250 cm
Dyeing of thread	Undyed	Undyed
Needles materials	Stainless Steel (silver or black colored)	Stainless Steel (silver colored)
Needle coating	Silicone coated	Information not publicly available
Needle curvatures	1/2, 3/8, and straight	1/2, 1/4, 3/8, 5/8, and straight
Needle points	Cutting, taper cutting, taper and extracut	Taper point, reverse cutting, trocar point, cutting, round, micro-lancet
Needle length	11 mm to 50 mm	6 mm to 51 mm

Absorption time	Absorption of the sutures OPTIME® R is essentially complete at 42 days	Absorption of SAFIL® QUICK takes place after approximately 42 days.
Shelf-life	5 years	Information not publicly available
Ideal storage	Must be stored in its original packaging, at a temperature below 25°C, in a dry place and protected from light	Information not publicly available
Package description	36 devices units per carton box One device unit is placed in cardboard support inside a tear able aluminum pouch which is placed inside a secondary pouch of paper/PE peel pouch	12 or 36 devices units per box Devices placed in cardboard support inside a tear able aluminum pouch inside a paper/PE peel pouch

9. Summary of Testing

As per the FDA's Class II Special Control Guidance Document for Surgical Sutures, the subject device was subjected to the requirements of the United States Pharmacopeia (U.S.P) monograph for Synthetic Absorbable Sutures.

Testing included:

- Diameter following USP 43 <861>
- Tensile strength following USP 43 <881>
- Needle attachment following USP 43 <871>
- Length following USP 43- Absorbable surgical suture

Stability testing has been completed.

Results of USP performance and resorption testing demonstrate that the subject device meets USP performance requirements for absorbable sutures and is substantially equivalent to its predicate device.

The biological evaluation of OPTIME®R was performed in accordance with FDA guidance on the use of ISO 10993-1. The following test reports were provided in this submission:

- Cytotoxicity
- Sensitization
- Irritation
- Material mediated pyrogenicity
- Acute Systemic Toxicity
- Sub-acute/sub-chronic Toxicity
- Genotoxicity
- Chemical characterization and toxicological risk assessment
- Implantation
- Degradation

10. Conclusion

Based on the information provided within this 510(k) submission, Peters Surgical concludes that:

OPTIME®R is substantially equivalent to the predicate device Safil Quick Synthetic Absorbable Surgical Suture (K031286).