July 01, 2026

Winter Innovations, Inc.
Lia Winter
CEO
2450 Ej Chapman Dr., Suite 114
Knoxville, TN 37996

Re: K261021
Trade/Device Name: EasyWhip Family
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT, GAB
Dated: May 29, 2026
Received: May 29, 2026

Dear Lia Winter:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new

premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261021

Device Name
EasyWhip Family

Indications for Use *(Describe)*
The EasyWhip Family is indicated for use in approximation and/or ligation of soft tissues, including the use of allograft tissue for orthopedic surgeries.

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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"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."

510(k) SUMMARY
(K261021)

Sponsor/Applicant
Winter Innovations Inc.
2450 EJ Chapman Drive, Suite 114
Knoxville, TN 37996
(865) 205-5728

Contact Person:
Lia Winter, MS, MBA
Chief Executive Officer

Date of Preparation: June 30, 2026

Trade Name: EasyWhip® Family

Common Name: non-absorbable surgical suture and two-part needle system

Product Code: GAT

Classification Name: Suture, Non-Absorbable, Synthetic, Polyethylene

Regulation Number: 21 CFR § 878.5000

Device Class: II

Review Panel: General and Plastic Surgery

Predicate Device: K210675, EasyWhip®

Device Description & Intended Use
The EasyWhip® Family is a non-absorbable surgical suture system with a specialized two-part needle intended for soft tissue stitching in orthopedic procedures (Achilles, ACL, biceps, peroneal, etc.). The two-part needle system is designed to facilitate easy, fast, and accurate stitch placement with less variation. It enables stitch patterns that capture both sides of the tissue using a single needle pass.

The devices can be used to create multiple stitch patterns, including a whip stitch, a WhipLock™ stitch (which combines a whip stitch with a locking stitch similar to a Krackow stitch), and hybrid stitch configurations according to individual user needs and preferences. The design simplifies and standardizes existing manual suturing techniques by facilitating controlled stitch placement as a convenience to surgeons.

Devices are provided sterile and are intended for single use only. The devices meet applicable USP requirements for non-absorbable surgical sutures, except for diameter.

Indications for Use
The EasyWhip® Family is indicated for use in approximation and/or ligation of soft tissues, including the use of allograft tissue for orthopedic surgeries.

Technological Characteristics

The two-part needle system consists of (1) a Needle with a sharp tip and a receiver at the back end, and (2) an Insert that slides into the receiver of the Needle to temporarily connect the two components. The Needle and Insert are attached to opposite ends of a length of suture. When disconnected, the suture is straight; when connected, the suture forms a loop that allows both suture tails to pass through tissue with a single needle hole.

The suture is braided, non-absorbable ultra-high molecular weight polyethylene (UHMWPE) that is either undyed or dyed using color additives that are approved and comply with applicable FDA requirements of 21 CFR 70.5(c), and it is equivalent to FDA-cleared suture material. The needle components are fabricated from stainless steel and are comparable to materials used in predicate devices.

At a high level, the subject and predicate devices share the same fundamental technological characteristics, with only minor differences in device configurations as summarized in the table below.

Technological Characteristic	**EasyWhip® Family (Subject Device)**	**EasyWhip® (Predicate - K210675)**
Product Code, Regulation	GAT, 21 CFR 878.5000	Same
Indications for Use	… indicated for use in approximation and/or ligation of soft tissues, including use of allograft tissue for orthopedic surgeries.	Same
Principles of Operation	Uses a two-part needle attached to suture to place stitches in soft tissue for approximation and/or ligation.	Same
Technical Characteristics	Two-part needle attached to ends of suture. Two-parts temporarily connectable.	Same
Patient Contact Duration	Mixed: Needle – limited (≤24 hours), Suture – permanent (>30 days)	Same
Biocompatibility	Meets ISO 10993 requirements	Same
Sterilization	Sterile, Ethylene Oxide	Same
Device Materials	UHMWPE non-absorbable suture, stainless steel needle components, silicone, cyanoacrylate	Same
Needle Materials	Stainless Steel (300 and 400 series)	Stainless Steel (300 series)
Two-Part Needle Configuration	Needle components attached to both ends of suture	Same
Needle Length	1.78'' – 2.56''	2.04"
Needle Geometry	Straight – Curved	Straight
Needle Body	Solid	Hollow
Needle Tip	Taper-Point	Tri-beveled
Suture Size	USP Size 0 – Size 3&4, deviate for diameter	USP Size 2, oversize diameter
Suture Braid	Round – Flat	Round
Suture Length	30'' – 40'' total (15'' – 20'' working)	40" total (20'' working)
Suture Dye	chromium-cobalt-aluminum oxide, D&C Black No. 4	D&C Black No. 4
Suture Absorption	Non-Absorbable	Same
Performance	Meets USP surgical suture requirements, except for diameter	Same
Suture Diameter USP <861>	Round: 13.8 mils – 33 mils *deviate from USP diameter* Flat: 1.35 – 1.7 mm *differs from USP requirements*	19.7-24.8 mils *Oversized for USP*
Sutures-Needle Attachment USP <871>	Meets USP	Same
Tensile Strength USP <881>	Meets USP	Same

Non-clinical Testing
The EasyWhip® Family meets the requirements of the *Class II Special Controls Guidance: Surgical Sutures; Guidance for Industry and FDA* (June 2003).

Performance testing was conducted or referenced to support the safety and effectiveness at time zero and over the duration of the labeled shelf life, including evaluation of suture tensile strength (USP <861>), needle attachment strength (USP <871>), and diameter (USP <881>). Deviations in diameter are identified in labeling.

The suture component has been evaluated and demonstrated to be "MR Safe," posing no known hazards in MR environments.

Biocompatibility safety testing was performed in accordance with guidance document *Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and Testing within a Risk Management Process* (September 2023).

Testing supports that the EasyWhip® Family is as safe and effective as the predicate device.

Clinical Testing
This submission did not rely on clinical testing to demonstrate device performance and substantial equivalence.

Predetermined Change Control Plan (PCCP)
This submission includes a Predetermined Change Control Plan (PCCP) for the EasyWhip® Family. The PCCP establishes a framework for managing pre-planned modifications:

Planned Modification	Test Methods and Validation Activities	Communication to Users, as needed
Size Changes size range expanded for additional suture sizes ranging from 5-0 to 5 (5-0, 4-0, 3-0, 2-0, 0, 2, 3&4, and 5)	Suture diameter conformance to USP <861>, suture tensile strength conformance to USP <881>, and suture-needle attachment strength testing to USP <871> will be performed or verified, as applicable, in accordance with the Modification Protocol to confirm that the device meets applicable physical and mechanical performance requirements.	Each device configuration will have device-specific labeling according to Surgical Sutures - Class II Special Controls Guidance Document for Industry and FDA Staff (June 3, 2003), which will serve as the primary mechanism for communication of the implemented modification to users.
Color Changes FDA-compliant and cleared color additives Green Pigment 7 and D&C Violet No. 2	Biocompatibility evaluation, including cytotoxicity testing in accordance with ISO 10993-5 and FDA guidance, will be performed in accordance with the Modification Protocol to confirm that the modified device meets applicable cytotoxicity requirements.	Each device configuration will have device-specific labeling according to Surgical Sutures - Class II Special Controls Guidance Document for Industry and FDA Staff (June 3, 2003), which will serve as the primary mechanism for communication of the implemented modification to users.

Combined Size and Color Changes (outlined above)	Suture diameter conformance to USP <861>, suture tensile strength conformance to USP <881>, and suture-needle attachment strength testing to USP <871> will be performed or verified, as applicable, in accordance with the Modification Protocol to confirm that the device meets applicable physical and mechanical performance requirements. Biocompatibility evaluation, including cytotoxicity testing in accordance with ISO 10993-5 and FDA guidance, will be performed in accordance with the Modification Protocol to confirm that the modified device meets applicable cytotoxicity requirements.	Each device configuration will have device-specific labeling according to Surgical Sutures - Class II Special Controls Guidance Document for Industry and FDA Staff (June 3, 2003), which will serve as the primary mechanism for communication of the implemented modification to users.

The PCCP describes the testing methods, validation activities, and acceptance criteria to be performed prior to implementation of modifications while ensuring the EasyWhip® Family continues to meet applicable performance and safety requirements and remains as safe and effective as the predicate device. The suture component of the device, including all sizes and colors in the PCCP, has been previously cleared by FDA and is obtained directly from the corresponding 510(k) holder with a letter of reference for performance and biocompatibility testing data. The performance evaluation activities referenced from the suture 510(k) clearance include suture diameter verification in accordance with USP <861> and suture tensile strength verification in accordance with USP <881>. Please note that the scope of the PCCP will be limited to attaching a needle to the previously cleared suture sizes (5-0, 4-0, 3-0, 2-0, 0, 2, 3&4, and 5) for the same indications mentioned above, and using suture colors (Green Pigment 7 and D&C Violet No. 2) that have also been previously cleared by the Agency. No new suture sizes or colors that the FDA has not previously reviewed will be added under the PCCP framework.

Users will be informed of modifications implemented under the PCCP through updated labeling specific to the applicable device modifications.

The PCCP includes a description of modifications, a modification protocol, traceability from modifications to the associated verification and validation activities, and an impact assessment.

Conclusion

The EasyWhip® Family is substantially equivalent to the legally marketed predicate EasyWhip® K210675. Any differences between the EasyWhip® Family and the predicate were evaluated with non-clinical testing, which demonstrated substantial equivalence to the predicate.