May 3, 2021

Winter Innovations, Inc.
Ms. Lia Winter
CEO
2450 EJ Chapman Drive, Suite 114
Knoxville, Tennessee 37996

Re: K210675
Trade/Device Name: EasyWhip™
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: March 1, 2021
Received: March 5, 2021

Dear Ms. 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 (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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210675

Device Name
EasyWhip™

Indications for Use *(Describe)*
EasyWhip™ 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.

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510(K) SUMMARY – EasyWhip™, K210675

Sponsor/Applicant:	Winter Innovations Inc. 2450 EJ Chapman Drive, Suite 114 Knoxville, TN 37996
Date Prepared:	March 01, 2021
510(k) Contact:	Lia Winter, MS-MBA Chief Executive Officer
Trade Name:	EasyWhip™
Common Name:	Polyethylene non-absorbable surgical suture with two-part needle
Product Code, Classification Name, and Regulation Number	GAT; Suture, Non-Absorbable, Synthetic, Polyethylene; 21 CFR § 878.5000
Device Class:	II
Classification Panel:	General and Plastic Surgery
Device Description	EasyWhip™ is a non-absorbable suture with specialized needle that simplifies and standardizes existing manual suturing methods as a convenience to surgeons. It is designed to facilitate easy, fast, and accurate stitch placement with less variation. EasyWhip™ is versatile and enables several stitch techniques or patterns, including a whip stitch, a WhipLock™ stitch (which combines a whip stitch with a locking stitch similar to a Krakow stitch), and custom patterns according to individual user needs and preferences. EasyWhip™ consists of a single USP size 2, braided 40'' strand of suture (20'' loop) with portions of a two-part needle attached to each end. The needle portions consist of a tip with a sharp point and a dull insert that slides within the needle tip during stitching. The suture is non-absorbable Ultra-High Molecular Weight Polyethylene (UHMWPE) dyed black (D&C Black #4 not to exceed 1.0% by weight). The device is provided sterile for single use only. EasyWhip™ meets all surgical suture requirements established by USP for non-absorbable surgical sutures, except for oversize diameter.
Indications for Use	EasyWhip™ is indicated for use in approximation and/or ligation of soft tissues, including the use of allograft tissue for orthopedic surgeries.
Substantial Equivalence	EasyWhip™ claims substantial equivalence to the currently marketed primary predicate Teleflex Force Fiber Suture cleared under 510(k) K191268 on 6/11/2019. Any differences between EasyWhip™ and the predicate are considered minor and do not raise new or different questions of safety and effectiveness.

Technological Characteristics	EasyWhip™ is a non-absorbable suture with specialized needle that simplifies and standardizes suturing techniques. The suture component of the device is identical to the primary predicate Teleflex Force Fiber UHMWPE Suture K191268. The needle components of the device are fabricated from stainless steel, which is identical or substantially equivalent to materials used in the predicate device. The needle component of EasyWhip™ differs from conventional needles and the predicate device in that it has a unique two-part design with a needle tip and connectable rod/insert. The two needle components are fixed to ends of a length of suture. They can be connected to create a continuous loop of suture and disconnect to create a straight length of suture, which facilitates easier stitching and creation of patterns that cannot be made with conventional needles. Conventional suture needles are typically only one part. The attachment of a needle and rod/insert to the predicate device 510(k) cleared suture does not raise new or different questions of safety or efficacy. Testing supports that EasyWhip™ is as safe and effective as the currently marketed predicate device.
Summary of Testing	EasyWhip™ was evaluated in accordance with the recommendations in the Class II Special Controls Guidance: Surgical Sutures; Guidance for Industry and FDA; June 2003. EasyWhip™ was tested in accordance with the USP for non-absorbable surgical sutures for suture diameter, tensile strength, and needle attachment. EasyWhip meets all USP requirements, with the exception of an oversize in diameter, which is identified in the labeling. The device has been evaluated through biological safety tests as outlined in Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices -Part 1: Evaluation and testing within a risk management process"; September 2020. Results support that the device is biocompatible. Packaging and device stability evaluations were performed to support that device packaging will maintain a sterile barrier and that device performance is maintained for the entirety of the proposed shelf life. *Ex vivo* testing was performed to confirm functionality of the specialized needle and to evaluate biomechanical performance of grafts stitched with EasyWhip™. Results support that the device functions as intended. The suture component has been tested to demonstrate it is "MR Safe" and poses no known hazards in MR environments.
Conclusion	Conclusions drawn from the comparative non-clinical tests demonstrate that EasyWhip™ is as safe, as effective, and performs as well as or better than the identified legally marketed device.