510(K) SUMMARY – EasyWhip™, K210675

Sponsor/Applicant:	Winter Innovations Inc. 2450 EJ Chapman Drive, Suite 114 Knoxville, TN 37996
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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.