Special 510(k) Summary

SafetyFix Easy Out System

K 180753

1. Submission Sponsor

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3. Date Prepared

22 March 2018

4. Purpose of the Submission

The purpose of this notification is to seek clearance for the modifications to the Easy Out system to: 1) Change the name to SafetyFix Easy Out System; 2) Incorporate the addition of cannulated screws; and 3) Incorporate the addition of a modified screw head for the cannulated screws.

5. Device Identification

Trade/Proprietary Name: SafetyFix Easy Out System

Common/Usual Name: Screw, Fixation, Bone

Classification Name:	Smooth or threaded metallic bone fixation fastener
Regulation Number:	888.3040
Product Code:	HWC
Device Class:	Class II
Classification Panel:	Orthopedic

6. Legally Marketed Predicate Device

Primary Predicate:	K141401, Easy Out system, SafetyFix Medical Technologies, Inc. (formally known as Feet For Life Podiatry Centers)
Secondary Predicates:	K071092, Asnis™ Micro Cannulated Screw, Howmedica Osteonics Corp.
	K014154, Vilex/Duval/Orthex Cannulated Bone Screw Double Thread, Vilex, Inc.

7. Indications for Use Statement

The SafetyFix Easy Out System is indicated for temporary internal fixation and stabilization of osteotomies and fractures during normal healing of ankle, elbow and small bones such as those in the foot and wrist.

8. Device Description

The SafetyFix Easy Out System is an implant device previously cleared by the FDA for temporary internal fixation and stabilization of osteotomies and fractures during normal healing (Easy Out K141401). The only changes from the previously cleared device are the name change, addition of cannulated screws and the addition of a cannulated screw head option. There are no other changes to the SafetyFix Easy Out System when compared to the device cleared under K141401.

The SafetyFix Easy Out System consists of various cannulated and partially threaded solid screws designed to create lag compression and used for temporary internal fixation small bones and fragments. The SafetyFix Easy Out bone screws are self-tapping, self-drilling screws with thread diameters of 2.0, 2.5, 3.0, 3.5 and 4.0 mm, and lengths that range from 8 to 60 mm. All compression screws are fabricated from medical grade titanium alloy (per ASTM F-136). Associated instrumentation is available. All compression screws are offered non-sterile, for sterilization prior to use.

9. Description of Modification

This is a Special 510(k): Device Modification Submission. The basis for this submission is to: 1) Change the product name to SafetyFix Easy Out System; 2) Incorporate the addition of cannulated screws: and 3) Incorporate the addition of a modified screw head option for the cannulated screws. The verification activities have been summarized to demonstrate that the cannulated screws have equivalent dynamic and static testing results as the screws cleared in K141401.

10. Substantial Equivalence Discussion

The SafetyFix Easy Out System intended use and indications for use (cleared under K141401) remain identical. There have been no changes made to the principles of operation, manufacturing processes, or materials from those that were previously cleared. Other than the incorporation of the design modifications described above, there have been no further modifications to the device.

Table 5A – Comparison of Characteristics

Manufacturer	**SafetyFix Medical Technologies, Inc.**	**Feet for Life Podiatry Centers**	**Similarities and Differences**
Trade Name	**SafetyFix Easy Out**	**Easy Out**	
510(k) Number	K180753	K141401	Not applicable
Common Name	Screw, Fixation, Bone	Screw, Fixation, Bone	Identical
Product Code	HWC	HWC	Identical
Regulation Number	21 CFR § 888.3040	21 CFR § 888.3040	Identical
Regulation Name	Smooth or threaded metallic bone fixation fastener	Smooth or threaded metallic bone fixation fastener	Identical
Intended Use	Intended to be used for internal bone fixation	Intended to be used for internal bone fixation	Identical
Indications for Use	The SafetyFix Easy Out System is indicated for temporary internal fixation and stabilization of osteotomies and fractures during normal healing of ankle, elbow and small bones such as those in the foot and wrist.	The Easy Out system is indicated for temporary internal fixation and stabilization of osteotomies and fractures during normal healing of ankle, elbow and small bones such as those in the foot and wrist	Identical, apart from the product name change
Overall Design	Medical grade titanium alloy, partially threaded Solid and Cannulated screws	Medical grade titanium alloy solid, partially threaded screws	The device modification is the addition of the cannulated screws to K141401, which only included solid screws. While minor design differences exist, the intended use and principle of operation is substantially equivalent. Performance testing demonstrates the safety and efficacy of the cannulated screws.
Material	Medical grade titanium alloy (Ti-6Al-4V ELI) per ASTM F-136	Medical grade titanium alloy (Ti-6Al-4V ELI) per ASTM F-136	Identical
Complies with ISO 10993-1	Yes	Yes	Identical
Noncannulated	Ø2.0, Ø2.5, Ø3.0, Ø3.5,	Ø2.0, Ø2.5, Ø3.0, Ø3.5,	Identical screw options

Manufacturer	SafetyFix Medical Technologies, Inc.	Feet for Life Podiatry Centers	Similarities and Differences
Trade Name	**SafetyFix Easy Out**	**Easy Out**	
Screw Diameters	and Ø4.0 mm	and Ø4.0 mm	
Noncannulated Screw Lengths	12 to 60 mm	12 to 60 mm	Identical
Cannulated Screw Diameters	Ø2.0, Ø2.5, Ø3.0, and Ø4.0 mm Wedge head option available in Ø2.0 mm only	Not available; Removed from K141401	Different – This submission adds the cannulated screws. Performance testing confirms the equivalence to the data provided in K141401. Static and dynamic 3-point bend tests, static torsional tests and axial pull-out tests were conducted to support substantial equivalence. The addition of the cannulated screws does not raise any new safety or efficacy concerns
Cannulated Screw Lengths	8 to 60 mm Wedge head option available in 8 to 30 mm only	Not available; Removed from K141401	Different – This submission adds the cannulated screws. Performance testing confirms equivalence to the data provided in K141401. The addition of the cannulated screws does not raise any new safety or efficacy concerns
Compression mechanisms	Spherical Compression Ball with Square Screw Head	Spherical Compression Ball with Square Screw Head	Identical
	Compression Wedge Head design with a Hex driver	Not applicable	Different – the subject system introduces a more conservative compression wedge head design. The addition of the modified screw head does not raise any new safety or efficacy concerns.
Sterile	Provided Non-sterile	Provided Non-sterile	Identical
Single-Use	Yes	Yes	Identical
Standards complied with	ASTM F1264-03 (07), ASTM F543-07e1	ASTM F1264-03 (07), ASTM F543-07e1	Identical

11. Non-Clinical Performance Data

Performance testing was conducted to further characterize the performance of the SafetyFix Easy Out System's addition of the cannulated screws and modified screw head. The device functioned as intended and the test results demonstrate substantial equivalence to the previously cleared device (K141401). Static and dynamic 3-point bend tests, static torsional tests and axial pull-out tests were conducted to support substantial equivalence. Static and dynamic Three Point Bend testing was conducted in accordance with ASTM F1264-03 (07), *Standard Specification and Test Method for Intramedullary*

Fixation Devices. Additionally, testing was conducted to characterize the torsional strength of the screw as well as axial pullout per ASTM F543-07(e1), *Standard Specification and Test Methods for Metallic Medical Bone Screws*.

Furthermore, an engineering analysis was performed against the predicates to evaluate torsional strength and pullout strength performance.

The results of this testing demonstrate that SafetyFix Easy Out System performs as intended and that the device is substantially equivalence to the previously cleared device (K141401).

12. Statement of Substantial Equivalence

The SafetyFix Easy Out System has the Identical intended use, principles of operation, and performance to the predicate device. The additional design characteristics of the modified device were tested in accordance with design controls, and verified to meet specifications. The SafetyFix Easy Out System, as modified, is determined to be substantially equivalent to the Easy Out system device cleared in K141401.