



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Ascent Medical, LLC
% Mr. Al Lippincott
Engineering Consulting Services, Incorporated
3150 E. 200th Street
Prior Lake, Minnesota 55372

October 13, 2015

Re: K150693

Trade/Device Name: PHIN-FX Cannulated Lag Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: October 1, 2015
Received: October 8, 2015

Dear Mr. Lippincott:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) NUMBER: **K150693**

DEVICE NAME: **Ascent Medical – PHIN-FX Cannulated Lag Screw System**

The ***intended use*** of the Ascent Medical – PHIN-FX Cannulated Lag Screw System is to draw two or more aligned bone fragments together in an adult patient.

The Ascent Medical – PHIN-FX Cannulated Lag Screw System **is indicated for use** for small and long bone fractures, arthrodesis and osteotomy fixation as follows:

The Mini and Small - PHIN-FX Cannulated Lag Screw Systems are indicated for small bone fractures and reduction of the glenoid and humeral head, medial malleolus and fibula, distal tibia and pilon, radius and ulna, olecranon and distal humerus, patella, pelvis, tarsal and fusions, metatarsal and phalangeal and with osteotomies, small bones in the hand and wrist, ligament fixation when appropriate, small joint fusion, and other small bone fragment cancellous fractures and osteotomies where the size of the screw/washer adapts to the specific indication.

The Large – PHIN-FX Cannulated Lag Screw System is indicated for long bone fractures and reduction of the intracapsular hip, slipped capital femoral epiphysis with proper image fluoroscopy for proper screw placement, femoral condyles, tibia condyles, ankle arthrodesis, large bone calcaneus and talus, acetabulum, sacroiliac and pelvic disruptions, and other areas where accurate screw/washer placement in long bone is required and adapts to the specific indication.

The Ascent Medical – PHIN-FX Cannulated Lag Screw System ***is not*** for spinal use.

Prescription Use **XXXX** AND/OR Over-The-Counter-Use _____
 (Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ascent Medical – PHIN-FX Cannulated Lag Screw System - **K150693** - **510(k) Summary**:

510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990

510(k) Summary

NAME OF FIRM: Ascent Medical, LLC
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Jackson, MS 39211
USA
www.ascentmedical.com

510(k) FIRM CONTACT: Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372
Tel. No. 952-492-5858
e-mail: allippincott@msn.com

DATE: July 21, 2015

TRADE NAME: **Ascent Medical – PHIN-FX Cannulated Lag Screw System**

COMMON NAME: Cannulated Bone Screw & Washer System

DEVICE NAME: Screw, Fixation, Bone
Washer, Bolt, Nut, Non-Spinal, Metallic

CLASSIFICATION: Smooth or Threaded Metallic Bone Fixation Fastener,
Class II (21 CFR, Sec. 888.3040)

Single/multiple component metallic bone fixation appliances and
accessories, Class II (21CFR, Sec. 888.3030)

DEVICE PRODUCT CODE: **HWC**

**SUBSEQUENT
PRODUCT CODE:** **HTN**

**SUBSTANTIALLY
EQUIVALENT DEVICE** Vilex – Cannulated Bone Screws (**K991197, K014154**)
Synthes – Cannulated Screws & Washers (**K012945, K962823,
K963192, K963172, K021932 & K962011**)
Zimmer/Pioneer – Cannulated Screw & Washer System (**K102903,
K003496 & K142442**)
Instratek – Mini Cannulated Screws (**K120493**)
Acumed - Cannulated Screw System (**K123890**)
I.T.S. GmbH – Cannulated Screws (**K060156**)

Ascent Medical – PHIN-FX Cannulated Lag Screw System - K150693 - 510(k) Summary:**DEVICE DESCRIPTION:**

The *Ascent Medical – PHIN-FX Cannulated Lag Screw System* is a complement of various cannulated bone screws consisting of a 1). Mini Set of 2.0mm, 2.5mm, 3.0mm; 2). Small Set of 3.5mm, 4.0mm, 5.0mm; and 3). Large Set of 6.5mm and 7.3mm sizes with a Short or Long Thread length in numerous screw lengths to be used by the surgeon for various indications in the fracture fixation of small and long bone(s) in the human anatomy. All screws feature a cancellous thread form and are pre-drilling, self-tapping, and back-tapping (if removal is necessary) in design. All screws are used in conjunction with a appropriate sized Guide Wire and x-ray imaging for precise placement in bone across the fracture/osteotomy site. Associated matched size Washers for each screw size system are available for thin cortex or osteopenic bone where the screw head may break through. All *Ascent Medical – PHIN-FX System* cannulated bone screws & washers are manufactured from either high strength 316LVM Stainless Steel or 6-4 Alloyed Titanium materials. The titanium screws and washers are color anodized as a surface treatment for size recognition. A full compliment of instrumentation is available for use with the system. All implants and instrumentation are designated 'Non-sterile' in a tray/case system for 'single use' and sterilization by the end user.

INTENDED USE:

The *intended use* of the *Ascent Medical – PHIN-FX Cannulated Lag Screw System* is to draw two or more aligned bone fragments together in an adult patient.

The *Ascent Medical – PHIN-FX Cannulated Lag Screw System* **is indicated for use** for small and long bone fractures, arthrodesis and osteotomy fixation as follows:

The *Mini and Small - PHIN-FX Cannulated Lag Screw Systems* are indicated for small bone fractures and reduction of the glenoid and humeral head, medial malleolus and fibula, distal tibia and pilon, radius and ulna, olecranon and distal humerus, patella, pelvis, tarsal and fusions, metatarsal and phalangeal and with osteotomies, small bones in the hand and wrist, ligament fixation when appropriate, small joint fusion, and other small bone fragment cancellous fractures and osteotomies where the size of the screw/washer adapts to the specific indication.

The *Large – PHIN-FX Cannulated Lag Screw System* is indicated for long bone fractures and reduction of the intracapsular hip, slipped capital femoral epiphysis with proper image fluoroscopy for proper screw placement, femoral condyles, tibia condyles, ankle arthrodesis, large bone calcaneus and talus, acetabulum, sacroiliac and pelvic disruptions, and other areas where accurate screw/washer placement in long bone is required and adapts to the specific indication.

The Ascent Medical – PHIN-FX Cannulated Lag Screw System *is not* for spinal use.

Ascent Medical – PHIN-FX Cannulated Lag Screw System - K150693 - 510(k) Summary:

EQUIVALENCE:	The <u>Ascent Medical - PHIN-FX Cannulated Lag Screw System</u> is Substantially Equivalent(SE) to the predicate systems (as listed). No nonclinical testing was used in the determination of substantial equivalence.
SUMMARY OF TECHNOLOGICAL CHARACTERISTICS	The <u>Ascent Medical – PHIN-FX Cannulated Lag Screw System</u> is <u>Similar</u> in Material, Design, and Indications to the listed predicate devices.
CONCLUSION:	The <u>Ascent Medical – PHIN-FX Cannulated Lag Screw System</u> has similar indications for use, materials, dimensions, and designs when compared to the predicate devices. An engineering/dimensional comparison to the predicate devices was performed to demonstrate Substantial Equivalence (SE). Based on these similarities, the <u>Ascent Medical – PHIN-FX Cannulated Lag Screw System</u> is substantially equivalent to the predicates identified in the 510(k) Summary.