



Food and Drug Administration
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Fusion Orthopedics, LLC
% J.D. Webb
Regulatory Consultant
The Orthomedix Group, Inc.
1001 Oakwood Blvd.
Round Rock, Texas 78681

August 7, 2017

Re: K170038

Trade/Device Name: FuzeFix Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: July 25, 2017
Received: July 28, 2017

Dear J.D. Webb:

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" (21 CFR 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,

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 (if known)

K170038

Device Name

FuzeFix Screw System

Indications for Use (Describe)

The FuzeFix Mini System is intended for use in the stabilization and fixation of bone fractures, osteotomies, non-unions, and reconstruction, tendon reattachment, and arthrodesis of the hand, foot, wrist, and ankle. The FuzeFix Mini System is indicated for: scaphoid fractures, capitate fractures, metacarpal fractures, phalangeal fractures, ulnar styloid fractures, small joint fusions, humeral head fractures, intercarpal fractures, tarsal fusions, patellar fractures, interfragmentary ulnar fractures, small hand and wrist bone fractures, forefoot interfragmentary fractures, lunate fractures, trapezial fractures, metatarsal fractures, radial head fractures, osteo-chondral fractures, glenoid fractures, interphalangeal fractures, malleolar fractures, metaphyseal fractures, interfragmentary radius fractures, distal metatarsal osteotomies, midfoot interfragmentary fractures. Not intended for use in the spine.

The FuzeFix Large System is intended for use in the stabilization and fixation of bone fractures, osteotomies, non-unions, and reconstruction, tendon reattachment, and arthrodesis of the hand, foot, wrist, and ankle. The FuzeFix Large System is indicated for: joint reconstructions, joint fusions, multiple fragment joint fractures, simple metaphyseal fractures, fractures of the wrist, ankle, elbow, and shoulder, metatarsal fractures and other fractures of the foot, ligament fixation of the proximal humerus, malleolar fractures, navicular fractures, fractures of the calcaneus, fractures of the talus, arthrodesis of the ankle joint, and fractures of the tarsal region. The devices and implants are not intended for use in the spine.

The FuzeFix Headless FT System is intended for use in the stabilization and fixation of bone fractures, osteotomies, non-unions, and reconstruction, tendon reattachment, and arthrodesis of the hand, foot, wrist, and ankle. The FuzeFix Headless FT System is indicated for: Osteochondral fragments (talar vault, femoral condyle), apical fragments (radial head, patellar rim, navicular, metacarpal/metatarsal), cancellous fragments (talus), Carpal, meta-carpal, and small hand bone, tarsal and metatarsals, phalanges, Intra-articular fractures, ankle, proximal and distal humerus, proximal and distal radius, proximal and distal ulna, osteochondral fixation and fractures, Osteochondritis Dissecans, Fixation of fractures and osteotomies about the knee, Oblique fractures of the fibula, Reconstructive surgeries of the foot, and malleolar fixation. Not intended for use in the spine.

The FuzeFix Twist Off System is intended for use in the stabilization and fixation of bone fractures, osteotomies, and for bone reconstruction of the hand and foot. The FuzeFix Twist Off System is indicated for: fixation of small bone fragments, Weil osteotomy, mono-cortical fixation, osteotomies and fractures fixation in the foot and hand.

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: FuzeFix Screw System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

May 16	May 16, 2017
Submitted By	Fusion Orthopedics, LLC 4135 S. Power Rd., Suite 110 Mesa, AZ 85212 800-403-6876
Contact	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199 Tele e-mail: jdwebb@orthomedix.net
Trade Name	FuzeFix Screw System
Common Name	Bone screws
Classification Name	Smooth & threaded metallic bone fixation fasteners
Class	II
Product Code	HWC
CFR Section	21 CFR section 888.3040
Device Panel	Orthopedic
Primary Predicate Device	Osteomed ExtremiFix Cannulated Screw System, Wright Medical (K063298 / K151021)
Secondary Predicate Devices	CHARLOTTE™ Snap-Off Screw, Wright Medical (K043583) Cannulated Bone Screws, OrthoPro, LLC (K042310) Tiger Cannulated Screw System, Trilliant Surgical (K081510) Synthes Cannulated Screws, Synthes (K963172 / K021932) Acutrak® 2 Screw System, Acumed (K944330) Arthrex Compression FT Screws, Arthrex (K132217)
Reference Predicate Devices	Kangli Pedicle Screw System, Suzhou Kangli Orthopaedics Instrument Co., Ltd (K140053 / K142290)
Device Description	The FuzeFix Screw System consists of headed and headless, partial and full threaded cannulated, self-compressive screws and snap off screws and washers for the management of orthopedic osteotomies and trauma. The screws are self-drilling, self-tapping. The system consists of multiple screw lengths and diameters, and the necessary instruments to facilitate the placement of these implants.
Materials	Titanium alloy, Ti-6Al-4V (ASTM F136)
Substantial Equivalence Claimed to Predicate Devices	The FuzeFix Screw System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	The FuzeFix Mini System is intended for use in the stabilization and fixation of bone fractures, osteotomies, non-unions, and reconstruction, tendon reattachment, and arthrodesis of the hand, foot, wrist, and ankle. The FuzeFix Mini System is indicated for: Scaphoid fractures, capitate fractures, metacarpal fractures, phalangeal fractures, ulnar styloid fractures, small joint fusions, humeral head fractures, intercarpal fractures, tarsal fusions, patellar fractures, interfragmentary ulnar fractures, small hand and wrist bone fractures, forefoot interfragmentary fractures, lunate fractures, trapezial fractures, metatarsal fractures, radial head fractures, osteo-chondral fractures, glenoid fractures, interphalangeal fractures, malleolar fractures, metaphyseal fractures, interfragmentary radius fractures, distal metatarsal osteotomies, midfoot interfragmentary fractures. Not intended for use in the spine.

<p>Indications for Use</p>	<p>The FuzeFix Large System is intended for use in the stabilization and fixation of bone fractures, osteotomies, non-unions, and reconstruction, tendon reattachment, and arthrodesis of the hand, foot, wrist, and ankle. The FuzeFix Large System is indicated for:</p> <p>Bone reconstructions, joint fusions, multiple fragment joint fractures, simple metaphyseal fractures, fractures of the wrist, ankle, elbow, and shoulder, metatarsal fractures and other fractures of the foot, ligament fixation of the proximal humerus, malleolar fractures, navicular fractures, fractures of the calcaneus, fractures of the talus, arthrodesis of the ankle joint, and fractures of the tarsal region.</p> <p>The devices and implants are not intended for use in the spine.</p>			
	<p>The FuzeFix Headless FT System is intended for use in the stabilization and fixation of bone fractures, osteotomies, non-unions, and reconstruction, tendon reattachment, and arthrodesis of the hand, foot, wrist, and ankle. The FuzeFix Headless FT System is indicated for:</p> <p>Osteochondral fragments (talar vault, femoral condyle), apical fragments (radial head, patellar rim, navicular, metacarpal/metatarsal), cancellous fragments (talus), carpal, meta-carpal, and small hand bone, tarsal and metatarsals, phalanges, Intra-articular fractures, ankle, proximal and distal humerus, proximal and distal radius, proximal and distal ulna, osteochondral fixation and fractures, osteochondritis dissecans, Fixation of fractures and osteotomies about the knee, oblique fractures of the fibula, reconstructive surgeries of the foot, and malleolar fixation.</p> <p>Not intended for use in the spine.</p>			
	<p>The FuzeFix Twist Off System is intended for use in the stabilization and fixation of bone fractures, osteotomies, and for bone reconstruction of the hand and foot. The FuzeFix Twist Off System is indicated for: fixation of small bone fragments, Weil osteotomy, mono-cortical fixation, osteotomies and fractures fixation in the foot and hand.</p>			
<p>Technological Characteristics</p>		<p>FuzeFix Mini Screw System</p>	<p>Intratek Mini Cannulated Titanium Headed and Headless Screw Set</p>	<p>Osteomed ExtremiFix Cannulated Screw System</p>
	Intended use	Fixation of fractures of bones in foot, hand, wrist, & ankle	same	same
	Geometry	Headed/headless distal thread	same	same
	Material	Ti-6Al-4V alloy	same	same
	Sizes	Ø2-4 mm, length 8-50 mm	Included in FuzeFix range	Included in FuzeFix range
		<p>FuzeFix Mini Screw System</p>	<p>OrthoPro Cannulated Bone Screw</p>	<p>Trilliant Tiger Cannulated Screw System</p>
	Intended use	Fixation of fractures of bones in foot, hand, wrist, & ankle	same	same
	Geometry	Headed/headless distal thread	same	same
	Material	Ti-6Al-4V alloy	same	same
	Sizes	Ø2-4 mm, length 8-50 mm	Included in FuzeFix range	Included in FuzeFix range
		<p>FuzeFix Large Screw System</p>	<p>Osteomed ExtremiFix Cannulated Screw System</p>	<p>Synthes Cannulated Screws</p>
	Intended use	Fixation of fractures of bones in foot, hand, wrist, & ankle	same	same
	Geometry	Headed/headless distal thread	same	Headed, distal thread
	Material	Ti-6Al-4V alloy	same	same
	Sizes	Ø4.5-7.3 mm length 20-130 mm	Ø4.5-8.0 mm length 12-140 mm	Included in FuzeFix range
		<p>FuzeFix Headless Screw System</p>	<p>Acumed Acutrak® 2 Screw System</p>	<p>Arthrex Compression FT Screws</p>
Intended use	Fixation of fractures of bones in foot, hand, wrist, & ankle	same	same	
Geometry	Headless, fully threaded	same	same	
Material	Ti-6Al-4V alloy	same	same	
Sizes	Ø2.5-4.5 mm length 8-60 mm	Ø2.5-7.5 mm length 8-120 mm	Included in FuzeFix range	

	FuzeFix Twist Off Screw System	Wright CHARLOTTE™ Snap-Off Screw	
Intended use	Fixation of fractures of bones in foot & hand	same	same
Geometry	Drive shaft section snaps off after insertion Headed, fully threaded	same	same
Material	Ti-6Al-4V alloy	same	same
Sizes	Ø2.0-2.5 mm length 10-22 mm	Ø2.0-2.7 mm length 11-15 mm	
The FuzeFix Screw System's technological characteristics are similar to the predicate devices. Any differences do not affect the equivalency.			
Non-clinical Test Summary	<p>The following tests were conducted:</p> <ul style="list-style-type: none"> • Torque to Failure (ASTM F543-07 Annex A1) • Axial Pullout Strength (ASTM F543-07 Annex A2) • Driving/Insertion and Removal Torque (ASTM F543-07 Annex A3) • Engineering analyses • Pyrogenicity was evaluated using the Limulus amoebocyte lysate (LAL) assay. The testing demonstrated that the subject device meets the recommended maximum endotoxin level of 20 EU per device. <p>The results of these evaluations indicate that the FuzeFix Screw System is equivalent to predicate devices.</p>		
Clinical Test Summary	No clinical studies were performed		
Conclusions: Non-clinical and Clinical	Fusion Orthopedics, LLC considers the FuzeFix Screw System to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use		