June 26, 2020

Retrofix Screws, LLC
% Keith A. Barritt
Principal
Fish & Richardson P.C.
1000 Maine Avenue, S.W. Suite 1000
Washington, District of Columbia 20024

Re: K200226
Trade/Device Name: RetroFix
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: May 28, 2020
Received: May 29, 2020

Dear Keith Barritt:

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,

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200226

Device Name
Retrofix

Indications for Use *(Describe)*

The RetroFix screw is a cannulated tapered screw intended to be used as stand-alone bone screw for internal bone fixation for bone fractures of the ankle.

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
RetroFix Screws, LLC
RETROFIX Bone Screw

Submitter

(i) 510(k) Submitter

RetroFix Screws, LLC
1035 Lincolnton Road
Salisbury, NC 28144

(ii) 510(k) Submitter Contact

Keith A. Barritt
Fish & Richardson P.C.
1000 Maine Ave., S.W, Suite 1000
Washington, DC 20024
Phone: (202) 783-5070
Facsimile: (202) 783-2331
Email: barritt@fr.com

(iii) Preparation Date

June 25, 2020

Device

Trade or Proprietary Name:	RetroFix
Common Name:	screw, fixation, bone
Classification Name:	smooth or threaded metallic bone fixation fastener
Product Code:	HWC, 21 CFR 888.3040
Class:	2

Predicate Device

Arthrosurface Bone Screws predicate device (K#172383)

Device Description

The RetroFix screw is a cannulated tapered screw intended to be used as a stand-alone bone screw for internal bone fixation for bone fractures of the ankle.

The device is contraindicated for:

- Patients with a history of allergy to stainless steel, nickel, or titanium
- Pediatric patients with open growth plates (epiphysis)
- Ankle fracture with significant diastasis (to be left to surgeon's judgement)
- Active Infection
- Conditions which tend to retard healing such as blood supply limitations or previous infections
- Insufficient quantity or quality of bone to permit stabilization of the fracture
- Cases with malignant primary or metastatic tumors which preclude adequate bone support or screw fixations
- Foreign-body sensitivity
- Patients who cannot follow post-operative weight-bearing restrictions

The screw shaft has a predetermined length with a cannula extending through the length of the shaft. The shaft has a relatively large outside diameter proximal segment, a smaller outside diameter threaded distal segment, and a flared end.

The proximal segment and the distal segment are unitary. The cannula is adapted for use with a surgical K-wire. The screws have cortical threads and come in many different sizes, varying in diameter and lengths,

The device does not come sterile and must be sterilized prior to use.

Indications for Use

The RetroFix screw is a cannulated tapered screw intended to be used as a stand-alone bone screw for internal bone fixation for bone fractures of the ankle.

Comparison of Technological Characteristics

The RetroFix screw device has the same basic technological characteristics in terms of design, material, and chemical composition as the predicate device identified above. The RetroFix screw device does not have its own energy source.

A table comparing the two devices is shown below:

Comparison of RetroFix Screw device to Predicate Device

Device name	RetroFix Screw	Arthrosurface Bone Screws	Differences
Manufacturer	RetroFix Scres, LLC	Arthrosurface, Inc.	
510(K) No.	(Pending)	K172383	
Device classification name	Smooth or threaded metallic bone fixation fastener	Smooth or threaded metallic bone fixation fastener	
Product code	HWC	HWC	
Indications for Use	The RetroFix screw is a cannulated tapered screw intended to be used as a stand-alone bone screw for internal bone fixation for bone fractures of the ankle.	The Arthrosurface Bone Screws (2.0-3.0 mm solid and cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, and wrist. The Arthrosurface Bone Screws (3.5 mm and larger, solid and cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions in the ankle, foot, hand, wrist, shoulder, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur, and fibula.	The scope of the indications for use of the RetroFix screw is within the scope of the predicate device's authorized Indications for Use.
Principle of operation	Cannulated screws of various dimensions for bone fracture fixation	Cannulated screws of various dimensions for bone fracture fixation	
Material composition	RetroFix screws are 100% Ti-6AL-4V titanium alloy	Some screws are stainless steel and some are titanium alloy	

Device name	RetroFix Screw	Arthrosurface Bone Screws	Differences
	All accessories that come into direct or indirect contact with the patient (screw drive, drill bits, depth gauge, drill guide, and k-wire) are made of stainless steel or titanium (with the exception of the drive handle which is made of aluminum)	No accessories are identified in the 510(k) Summary for the Arthrosurface bone screws	All accessories for the RetroFix screws have been assessed for biocompatibility
Performance Characteristics	The RetroFix screws were tested pursuant to ASTM F543 and ASTM F1264 standards for mechanical strength	The Arthosurface screws were tested pursuant to ASTM F543 standard for mechanical strength	Both devices were tested pursuant to ASTM F543

Shelf Life Testing

Shelf-life testing is not applicable because of the low likelihood of time-dependent product degradation.

Material And Chemical Composition

RetroFix screws are 100% Ti-6AL-4V titanium alloy.

Performance Data Summary

The RetroFix screw device was tested using ASTM F543-17 for static torsion, driving torque, removal torque, and static axial pullout, as well as ASTM F1264-16 for both static and dynamic four-point bending strength.

There were no clinical tests performed for the RetroFix screw device.

Conclusion

Based on the non-clinical testing conducted of the physical properties of the RetroFix screw device in comparison to the predicate device identified above, and on the biocompatibility assessment of the device, it is concluded that the RetroFix screw device is substantially equivalent to the predicate device.