DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 7, 2015

Synchro Medical
% Mark F. Schenk
Mark F. Schenk Consulting
505 Berks Place
West Lawn, Pennsylvania 19609

Re: K151241
Trade/Device Name: Synchro-Medical TIGER TRACK® 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: June 8, 2015
Received: June 9, 2015

Dear Mr. Schenk:

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 yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151241

Device Name
Synchro-Medical TIGER TRACK® Screw System

Indications for Use *(Describe)*
The TIGER TRACK® screw system is intended for small bone extremities and large/long bone reconstruction fixation/ arthrodesis procedures for general use in skeletally mature individuals. The TIGER TRACK® screw system is intended to be permanently implanted without any other additional device and are delivered sterile.

The TIGER TRACK® screw system, for diameters 3.5mm or smaller(1.8mm, 2.2mm, 2.5mm, 2.9mm, 3.0mm), is indicated for use in fixation for small bone fractures or for small bone reconstruction including: mono or bicortical osteotomies in the foot or hand; distal or proximal metatarsal or metacarpal osteotomies; Weil osteotomy; fusion of the first metatarsalphalangeal joint and interphalageal joint; fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.); Akin type osteotomy; distal radius fractures (articular fragments). ulnar styloid fractures, radial head fractures, capirellumn fractures, humeral head fractures, glenoid fractures, intercarpal distal and proximal fusions, malleolar fractures, patellar fractures, osteochondral fractures, talonavicular fusions, tibeo-talar fusions, and cuboid fusions.

The TIGER TRACK® screw system, for diameters 4.5mm and 7.0mm, is indicated for use for fractures, corrective osteotomies, pseudoarthrosis, degenerative transformations of long bones in the hind foot and large bone intra-articular fractures of the humerus, femur, and tibia. The size of the chosen screw should be adapted to the specific indication.

The TIGER TRACK® screw system is not for spinal use. The devices described in this manual must be accompanied with a form of immobilisation suited to the pathology being treated.

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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Traditional 510(k) Summary

as required by section 807.92(c).

Synchro-Medical TIGER TRACK® Device

K151241

Submitter:	Synchro Medical 6 rue des Merisiers F-68920 Wettolsheim les Erlen FRANCE
Contact Person	Danilo Campani President Phone: +33(0)3 89 23 75 64 Fax:+33(0)3 89 27 14 52 Email: dcampani@synchro-medical.com
Date Prepared	07/07/2015
Device Class	Class II

Trade Name	TIGER TRACK®.
Common Name	Synchro-Medical TIGER TRACK® Screw System
Classification Name and Number	Smooth or threaded metallic bone fixation fastener 21 CFR 888.3040
Classification Panel:	Orthopedic
Product Code	HWC
Predicate Devices	(K043142 & K030900) Inion Ltd., OTPS™ Biodegradable Screws; (K131722), I.T.S GmbH, Extremity Fixation Systems; (K041189), Arthrex, TRIMit Family; (K071540) Small Bone Innovations International, SBI Titanium Threaded Pin, Percufix; (K041456) & (K070617), Fournitures Hospitalières Industries, Snap-off Screws & Cannulated Screws; (K895389), Biomet, (Ex-Depuy), S.O.C Pin; (K063298), OsteoMed L. P., Headless Cannulated Screw System; (K132912) In2Bones, DUAFIT Interphalangeal Implant; (K130859), Arthrosurface, Hammertoe Correction System, (K120739) Tornier, Aequalis Adjustable Modular Reverse Shoulder System; (K133036) Amendia, Apollo Suture Anchor System, (K133235) Threaded Peek K-Wire MTP Solutions, and (K022599) Newdeal K Wire.

Previous Submissions	There are no previous submissions
Device Description	The TIGER TRACK® screw system is intended for single use only, and is available in a range of different diameters, lengths and materials depending on the indication. The TIGER TRACK® screw system has two categories of screws: self-compressive screws and non-compressive screws. The self-compressive screws have a distal and proximal thread, separated by a cylindrical shaft where the fracture or osteotomy line should be placed. The difference of pitch between the distal and proximal thread provides compression between both segments. The TIGER TRACK® snap-off Weil screw doesn't have a proximal thread, the compression is done by its head and the distal thread. The non-compressive screws have a full thread allowing surgeons to only link both segments without any compression. All devices of the TIGER TRACK® screws system are monobloc components. The TIGER TRACK® screw system PEEK range is manufactured dry with grades of PEEK (Zeniva ZA-500) per ASTM F-2026 from Solvay Advanced Polymers released with predicate K133036, Titanium range is made of alloyed Titanium ISO 5832-3 / ASTM F-136 and released with predicate K131722, Snap-off threaded pin HV18XX range is made of Cobalt Chrome according to the ISO 5832-7 / ASTM F-1058 and released with predicate K120739. The feature design of the TIGER TRACK® screw system is substantially equivalent to the design features of other devices previously cleared for market.

Intended Use / Indications	The TIGER TRACK® screw system is intended for small bone extremity and large/long bone reconstruction fixation/arthrodesis procedures for general use in skeletally mature individuals. The TIGER TRACK® screw system is intended to be permanently implanted without any other additional device and are delivered sterile. The TIGER TRACK® screw system, diameters 3.5mm or smaller (1.8mm, 2.2mm, 2.5mm, 2.9mm, 3.0mm), is indicated for use in fixation small bone fractures or for small bone reconstruction including: mono or bicortical osteotomies in the foot or hand; distal or proximal metatarsal or metacarpal osteotomies; Weil osteotomy; fusion of the first metatarsalphalangeal joint and interphalageal joint; fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.); Akin type osteotomy; distal radius fractures (articular fragments). ulnar styloid fractures, radial head fractures, capirellumn fractures, humeral head fractures, glenoid fractures, intercarpal distal and proximal fusions, malleolar fractures, patellar fractures, osteochondral fractures, talonavicular fusions, tibeo-talar fusions, and cuboid fusions. The TIGER TRACK® screw system, for diameters 4.5mm and 7.0mm, is indicated for use for fractures, corrective osteotomies, pseudoarthrosis, degenerative transformations of long bones in the hind foot and large bone intra-articular fractures of the humerus, femur, and tibia. The size of the chosen screw should be adapted to the specific indication. The TIGER TRACK® screw system is not for spinal use. The devices described in this manual must be accompanied with a form of immobilisation suited to the pathology being treated

Materials:	All devices of the TIGER TRACK® screws system are monobloc components. The TIGER TRACK® screw system PEEK range is manufactured dry with grades of PEEK (Zeniva ZA-500) per ASTM F-2026 from Solvay Advanced Polymers released with predicate K133036, Titanium range is made of alloyed Titanium ISO 5832-3 / ASTM F-136 and released with predicate K131722, Snap-off threaded pin HV18XX range is made of Cobalt Chrome according to the ISO 5832-7 / ASTM F-1058 and released with predicate K120739.

Statement of Technological Comparison	The purpose of this submission is to obtain market clearance for the proposed the TIGER TRACK® Screw System. The TIGER TRACK® Screw System and its predicate devices have similar indications for use and similar functionality. All devices are manufactured using materials with a long history of use in orthopaedic implants.

Nonclinical Test Summary	The following tests were performed to demonstrate that the TIGER TRACK® Screw System is substantially equivalent to other predicate devices. • Pullout force per ASTM F564-10 • Torsional Strength per ASTM F-543 The results of these studies showed the TIGER TRACK® Screw System met the acceptance criteria.
Clinical Test Summary	No clinical tests were performed.

Conclusion	The TIGER TRACK® Screw System is substantially equivalent to its predicate devices. This conclusion is based upon the fact the TIGER TRACK® Screw System and its predicate devices have the same indications for use and have a similar design.