K120390 1/2

APR 10 2012

510(k) Summary

Summary of 510 (k) safety and effectiveness information upon which the substantial equivalence determination is based:

Prepared: February 6, 2012
Applicant: Solana Surgical, LLC
6363 Poplar Ave, Suite 434
Memphis, TN 38119
Contact: Louise Focht
901-818-1860

Common Name:	Screw, fixation, bone
Device Trade Name:	Sola Fix Twist Screw Implant System
Device Classification Name:	Smooth or threaded metallic bone fixation fastener.
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number:	21 CFR 888.3040
Product Code:	HWC
Predicate Device:	K050819 Charlotte Snap-Off Screw

Device Description:

The Solana Surgical Implant is a one-piece device made of Titanium Alloy intended to be used as a screw for bone fixation, fusion, osteotomy or reconstruction of the hand and foot. The implant is available in a range of sizes (6) including 2.0mm diameter and length range of 11-16mm. The screw driving portion of the screw is intended to separate from the screw head once the screw seats to the bone.

Intended Use:

The Solana Surgical LLC, Sola Fix Twist Screw Implant System is intended to provide fixation for fracture, fusion, osteotomy or reconstruction of the bones of the hand and foot.

Technological Characteristics:

Mechanical testing was performed according to ASTM F543 and an engineering/dimensional comparison to the predicate device was performed to demonstrate substantial equivalence. Based on the evaluations performed, the design and indications of the Solana Surgical screw are substantially equivalent to the predicates identified in the 510(k) submission. No new materials or processes are used in the development of this implant.

Substantial Equivalence – Non-Clinical Evidence:

Mechanical testing was performed according to ASTM F543 and an engineering/dimensional comparison to the predicate device was performed to demonstrate safety and efficacy. The devices were also evaluated to demonstrate they performed as expected.

Conclusions:

Similarities of the Solana Surgical device to its predicates include these devices being: intended for single use only, intended for surgical implantation longer than 30 days, system consisting of a series of implants, made of industry standard materials, with no new materials being introduced in the product, comparably sized, and indicated for the same uses. The evaluations performed and data provided in this application demonstrate that the Solana Surgical device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Solana Surgical, LLC
% Ms. Louise Focht
6363 Poplar Avenue
Suite 434
Memphis, TN 38119

APR 10 2012

Re: K120390
Trade/Device Name: Sola Fix Twist Screw Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: February 6, 2012
Received: February 7, 2012

Dear Ms. Focht:

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.

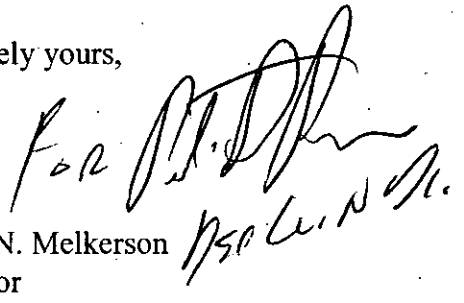
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120390
Device Name: Sola Fix Twist Screw Implant System
Indications for Use:

The Solana Surgical LLC, Sola Fix Twist Screw Implant System is intended to provide fixation for fracture, fusion, osteotomy or reconstruction of the bones of the hand and foot.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K120390