K132594

DEC 13 2013

6. 510(k) Summary

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

Prepared: August 15, 2013
Applicant: Solana Surgical, LLC
6363 Poplar Ave, Suite 312
Memphis, TN 38119
Joe Clift (Contact)
jclift@solanasurgical.com
(901) 818-1860

Common Name:	Plate, Fixation, Bone
Device Trade Name:	CrossCheck Plating System
Device Classification Name:	Single/Multiple component metallic bone fixation appliances and accessories
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number:	21 CFR 888.3030
Product Code:	HRS
Predicate Device(s):	Memometal Anchorage Bone Plate System: K083447 Integra Total Foot System K123000

Device Description:

The Solana Surgical, LLC CrossCHECK Plating System consists of a variety of bone plates and screws to be used in fixation fractures, osteotomies, and fusions in the extremities of the leg and arm including the hand and foot. The various plate designs use either 3mm or 3.5mm screws. Screws include both locking and non-locking designs. Lag screws and cross-hole plates are included for compression. Plate designs include MTP, Lapidus, and 2-7 Hole Utility plates. All plates and screws are manufactured from ASTM F136 Ti-6Al-4V ELI alloy. The design of the Solana Surgical implant is similar to the predicate devices. No new materials or processes are used in the development of this implant.

Indications for Use:

The Solana Surgical LLC, CrossCheck Plating System is indicated for stabilization and fixation of fresh fractures, revision procedures, joint fusion and reconstruction of small bones in the hand, feet, wrist, and ankles, fingers and toes. The system may be used in both pediatric and adult patients. The device is intended for single use.

Comparison to Predicate Device:

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, a 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 technological characteristics, principles of operation and mechanisms of action are the same as the predicates.

Summary of Device Testing:

The plates and screws of the subject device were evaluated per ASTM F382 "Standard Specification and Test Method for Metallic Bone Plates" and ASTM F543-07 "Standard Specification and Test Methods for Metallic Medical Bone Screws". Examples from the predicate device systems were used for comparison. The subject device met acceptance criteria and is substantially equivalent to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 13, 2013

Solana Surgical, LLC
Mr. Joe Clift
Senior Vice President Quality & Regulatory
6363 Poplar Avenue, Suite 312
Memphis, Tennessee 38119

Re: K132594
Trade/Device Name: CrossCheck Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: November 21, 2013
Received: November 22, 2013

Dear Mr. Clift:

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 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. 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 -S

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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132594

Device Name
CrossCheck Plating System

Indications for Use *(Describe)*

The Solana Surgical LLC, CrossCheck Plating System is indicated for stabilization and fixation of fresh fractures, revision procedures, joint fusion and reconstruction of small bones in the hand, feet, wrist, and ankles, fingers and toes. The system may be used in both pediatric and adult patients.

The device is intended for single use.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth L. Frank -S

Division of Orthopedic Devices