



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

SMV Scientific
% Mr. Kenneth Maxwell II
Regulatory and Quality Specialist
Empirical Testing Corporation
4628 Northpark Drive
Colorado Springs, Colorado 80918

November 25, 2015

Re: K152000

Trade/Device Name: SMV Bone Plate and Screw 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, HWC
Dated: October 28, 2015
Received: October 30, 2015

Dear Mr. Maxwell:

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 Parts 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" (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 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,

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: January 31, 2017 See PRA Statement on last page.
510(k) Number <i>(if known)</i> K152000	
Device Name SMV Bone Plate and Screw System	
Indications for Use <i>(Describe)</i> The SMV Bone Plate and Screw System is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia, and fibula, including, periarticular and intraarticular fractures.	
Type of Use (Select one or both, as applicable) <input checked="" type="checkbox"/> Prescription Use (Part 21 CFR 801 Subpart D) <input type="checkbox"/> 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) <i>(Signature)</i> 	

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

5. 510(K) SUMMARY

Submitter's Name:	SMV Scientific
Submitter's Address:	111 Sandra Muraida Way Unit 18A Austin, TX 78703
Submitter Contact Person:	Nephi Zufelt Chief Technology Officer 512.750.8622
Empirical Consulting Contact Person:	Kenneth C. Maxwell II Empirical Testing Corp. 719.291.6874
Date Summary was Prepared:	12 November 2015
Trade or Proprietary Name:	SMV Bone Plate and Screw System
Common or Usual Name:	Plate, Fixation, Bone Screw, Fixation, Bone
Classification:	Class II per 21 CFR §888.3030 & §888.3040
Product Code:	HRS, HWC
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The SMV Bone Plate and Screw System consists of implants and instruments designed for fixation to treat fractures, deformations, revisions and replantations of bones and bone fragments. The system features nineteen (19) types of plates, bone screws for fixation, and a set of instruments to facilitate installation and removal of the implants. The plates have screw holes, which allow for attachment to the bones or bone fragments. The plates are fabricated from medical grade stainless steel (ASTM F138), and offered in various widths and lengths. Plates and screws are provided non-sterile and sterile. The implants in this submission can be used with the screws cleared in K150981 and K150188.

INDICATIONS FOR USE

The SMV Bone Plate and Screw System is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia, and fibula, including, periarticular and intraarticular fractures.

The indications for use for the Bone Plate and Screw System is similar to that of the predicate devices listed in Table 5-1: Predicate Devices.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are identical between the subject and predicates:

- Indications for use
- Materials of manufacture
- Principles of operation

Table 5-1: Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K092609	3.5mm and 4.5mm Curved Narrow and Broad Locking Compression Plates (LCP), Straight Compression, Straight Reconstruction Bone Plates	Synthes	Primary
K001945	Medial Distal Tibia Plates	Synthes	Reference
K011335	One-Third Tubular DCL Plate, One-Third Tubular	Synthes	Reference
K020872	3.5 mm Broad LC-DCP Plates	Synthes	Reference
K082807	3.5mm and 4.5mm Locking Compression Plate (LCP) System	Synthes	Reference

PERFORMANCE DATA

The SMV Scientific Bone Plate and Screw System has been tested in the following test modes:

- Static Four-point Bending per ASTM F382
- Dynamic Four-point Bending ASTM F382

The results of this non-clinical testing show that the strength of the Bone Plate and Screw System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Bone Plate and Screw System is substantially equivalent to the predicate device.