DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 5, 2016

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

Re: K160946
Trade/Device Name: 4.0 and 6.5 Cancellous Bone Screw and Washer
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: October 21, 2016
Received: October 24, 2016

Dear Kenneth Maxwell II:

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,

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 *(if known)*
K160946

Device Name
4.0 and 6.5 Cancellous Bone Screw and Washer

Indications for Use *(Describe)*

The 4.0 SMV Scientific Cancellous Bone Screw and Washer is intended for fixation of fractures with medium fragments, e.g.: – tarsal and metatarsal fractures and fixation in metatarsal and phalangeal osteotomies – tarsometatarsal and metatarsophalangeal arthrodeses – ligament fixations – hallux valgus corrections. Additionally, the 4.0 SMV Scientific Cancellous Screw and Washer is intended for arthrodesis and osteotomies of small bones and small joints, including scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, patella, ulnar styloid, capitellum, radial head and radial styloid.

The 6.5 SMV Scientific Cancellous Bone Screw and Washer is intended for fixation of fractures with large fragments, e.g.: – femoral neck fractures – intercondylar femoral fractures – epiphyseolysis of the femoral head – ankle arthrodeses. Additionally, the 6.5 SMV Scientific Cancellous Screw and Washer is intended for reconstruction, osteotomy, and arthrodesis of various bones and bone fragments appropriate for the size of the device including joint fusions (arthrodesis) in the foot and 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)

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)*

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
Submitter's Name:	SMV Scientific
Date Summary was Prepared:	30 November 2016
Trade or Proprietary Name:	4.0 and 6.5 Cancellous Bone Screw and Washer
Common or Usual Name:	Smooth or threaded metallic bone fixation fastener
Classification:	Class II per 21 CFR §888.3040
Product Code:	HWC, HTN
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The SMV Scientific 4.0 and 6.5 Cancellous Bone Screw and Washer are manufactured from medical grade stainless steel. The SMV Scientific 4.0 and 6.5 Cancellous Bone Screw and Washer are offered in various diameters and lengths. The SMV Scientific 4.0 and 6.5 Cancellous Bone Screw and Washer are intended to provide fracture fixation. Implants are provided non-sterile with instructions for sterilization.

INDICATIONS FOR USE

The 4.0 SMV Scientific Cancellous Bone Screw and Washer is intended for fixation of fractures with medium fragments, e.g.: – tarsal and metatarsal fractures and fixation in metatarsal and phalangeal osteotomies – tarsometatarsal and metatarsophalangeal arthrodeses – ligament fixations – hallux valgus corrections. Additionally, the 4.0 SMV Scientific Cancellous Screw and Washer is intended for arthrodesis and osteotomies of small bones and small joints, including scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, patella, ulnar styloid, capitellum, radial head and radial styloid.

The 6.5 SMV Scientific Cancellous Bone Screw and Washer is intended for fixation of fractures with large fragments, e.g.: – femoral neck fractures – intercondylar femoral fractures – epiphyseolysis of the femoral head – ankle arthrodeses. Additionally, the 6.5 SMV Scientific Cancellous Screw and Washer is intended for reconstruction, osteotomy, and arthrodesis of various bones and bone fragments appropriate for the size of the device including joint fusions (arthrodesis) in the foot and ankle.

The indications for use for the Cancellous Screw and Washer is similar to that of the predicate devices listed in Table 5-1.

Table 5-1 Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Type
K111994	4.0 Cannulated Screws	Smith & Nephew	Primary
K000089	4.0mm and 5.0mm Locking Screws	Synthes	Additional
K963192	3.5mm and 4.0mm Cannulated Screws	Synthes	Additional
K061621	6.5mm Cancellous Screw	Synthes	Additional
K052483	Spherical Washers	Synthes	Additional

PERFORMANCE DATA

The SMV Scientific 4.0 and 6.5 Cancellous Bone Screw and Washer has been tested in the following test modes:

- Static Torsion per ASTM F543
- Static Axial Pullout per ASTM F543
- Static Removal Torque per ASTM F543

The results of this non-clinical testing show that the strength of the SMV Scientific 4.0 and 6.5 Cancellous Bone Screw and Washer 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 SMV Scientific 4.0 and 6.5 Cancellous Bone Screw and Washer is substantially equivalent to the predicate device.