DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 22, 2017

SMV Scientific
% Kenneth Maxwell
Regulatory And Quality Specialist
Empirical Testing Corporation
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K170021
Trade/Device Name: SMV Scientific Cannulated Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: April 20, 2017
Received: April 24, 2017

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 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,

Vincent J. Devlin -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 on last page.

510(k) Number *(if known)*
K170021

Device Name
SMV Scientific Cannulated Screws

Indications for Use *(Describe)*

The SMV Scientific 2.4mm and 3.0mm Cannulated Screws are intended for fixation of fractures and non-unions of small bones and small bone arthrodesis. Examples include, but are not limited to scaphoid and other carpal fractures, metacarpal and phalangeal fusions, osteotomies, and bunionectomies.

The SMV Scientific 3.5mm Cannulated Screws are intended for fixation of small bones and small bone fragments, such as fractures of the metatarsals, arthrodeses of the carpals and phalanges, steochondritis dissecans, and ligament fixation.

The SMV Scientific 4.5mm Cannulated Screws is intended for fracture fixation of long bones and long bone fragments.

The SMV Scientific 6.5mm and 7.3mm Cannulated Screws are intended for fracture fixation of large bones and large bone fragments, femoral neck fractures, slipped capital femoral epiphyses, as an adjunct to DHS in basilar neck fractures, tibial plateau fractures, ankle arthrodesis, pediatric femoral neck fractures, intercondylar femur fractures, and subtalar arthrodesis.

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
Date Summary was Prepared:	15 May 2017
Trade or Proprietary Name:	SMV Scientific Cannulated Screws
Common or Usual Name:	Smooth or threaded metallic bone fixation fastener
Classification:	Class II per 21 CFR §888.3040
Product Code:	HWC
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION

The SMV Scientific Cannulated Bone Screws consist of cannulated screws in a variety of lengths and diameters to accommodate different anatomic sizes of patients. The screws are provided non-sterile. Screws are manufactured from Stainless Steel per ASTM F138 or Titanium per ASTM F136 or F1295.

INDICATIONS FOR USE

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The SMV Scientific 6.5mm and 7.3mm Cannulated Screws are intended for fracture fixation of large bones and large bone fragments, femoral neck fractures, slipped capital femoral epiphyses, as an adjunct to DHS in basilar neck fractures, tibial plateau fractures, ankle arthrodesis, pediatric femoral neck fractures, intercondylar femur fractures, and subtalar arthrodesis.

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. Engineering analysis and dimensional comparison with the predicate devices supported substantial equivalence. 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**
K012945	2.4mm Cannulated Screw	Synthes	Primary
K962823	3.0mm Cannulated Screw	Synthes	Additional
K963192	3.5mm & 4.0mm Cannulated Screw	Synthes	Additional
K963172	4.5mm Cannulated Screw	Synthes	Additional
K962011 K021932	6.5 & 7.3mm Cannulated Screw	Synthes	Additional

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Cannulated Screws is substantially equivalent to the predicate device.