



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

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

March 28, 2016

Re: K160603

Trade/Device Name: SMV Scientific Schanz Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: February 29, 2016
Received: March 2, 2016

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

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:	29 February 2016
Trade or Proprietary Name:	SMV Scientific Schanz Screws
Common or Usual Name:	Smooth or threaded metallic bone fixation fastener.
Classification:	Class II per 21 CFR §888.3040 Device Classification
Product Code:	HWC
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

SMV Scientific Schanz Screws are manufactured from medical grade stainless steel. SMV Scientific Schanz Screws are offered in various diameters and lengths. SMV Scientific Schanz Screws are intended to provide fracture fixation.

INDICATIONS FOR USE

The SMV Scientific Schanz Screws are intended for use as external fixation for fracture fixation (open and closed); pseudoarthrosis or non-union of long bones; limb lengthening by epiphyseal or metaphyseal distraction; correction of bony or soft tissue deformity; correction of segmental bony or soft tissue defects; and joint arthrodesis.

The indications for use for the SMV Scientific Schanz Screw is similar to that of the predicate devices in Table 5-1 below.

Table 5-1 Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K040701	Self-Drilling Schanz Screws	Synthes	Primary

PERFORMANCE DATA

The SMV Scientific Schanz Screw has been tested in the following test modes:

- Static Four-point Bending per ASTM F1541-02

- Static Torsion per ASTM F1541-02

The results of this non-clinical testing show that the strength of the SMV Scientific Schanz Screw 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 Schanz Screw is substantially equivalent to the predicate device.