October 25, 2018

Summit MedVentures
% Meredith May
Vice President
Empirical Consulting LLC
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K182171
Trade/Device Name: SMV Scientific K-Wire and Pins
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: JDW, HTY
Dated: July 13, 2018
Received: August 10, 2018

Dear Meredith May:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Peter G. Allen -S
2018.10.25 23:44:02 -04'00'

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: 06/30/2020
See PRA Statement on last page.

510(k) Number *(if known)*
K182171

Device Name
SMV Scientific K-Wire and Pins

Indications for Use *(Describe)*

Devices (K-Wires and Steinmann Pins) are intended to be used as:
- Guide wires for osteosynthesis implants
- Accessories for external fixation (Steinmann Pins)
- Implants according to principles of fracture management

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

5. 510(K) SUMMARY

Submitter's Name:	Summit MedVentures
Submitter's Address:	7500 Rialto Blvd, Bldg 1, Ste 225 Austin, TX 78738
Contact Person:	Meredith Lee May MS, RAC Empirical Consulting 719.337.7579 MMay@EmpiricalConsulting.com
Date Summary was Prepared:	13 Jul 18
Trade or Proprietary Name:	SMV Scientific K-Wire and Pins
Common or Usual Name:	Wire Bone / K-Wire; Cerciage Wire, Steinmann Pin
Classification:	Class II per 21 CFR §888.3040
Product Code:	JDW, HTY

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The SMV Scientific K-Wire and Pin consists of K-Wire and Pins in a variety of lengths and diameters to accommodate different anatomic sizes of patients. The devices are provided non-sterile. All devices are manufactured from medical grade Stainless Steel or Titanium alloys.

INDICATIONS FOR USE

Devices (K-Wires and Steinmann Pins) are intended to be used as:

- Guide wires for osteosynthesis implants
- Accessories for external fixation (Steinmann Pins)
- Implants according to principles of fracture management

TECHNOLOGICAL CHARACTERISTICS

SMV Scientific K-Wire and Pins are made from 316L Stainless Steel per ASTM F138 or ISO 5823-3 or Titanium alloy (Ti-6Al-4V ELI) per ASTM F136 or ISO 5832-1. The subject and predicate devices have similar technological characteristics, including intended use, materials of manufactur, design, dimensions, and sizes.

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K131459	aap Wire Bone / K-Wire; Cerciage Wire, Steinmann Pin	aap Implantante AG	Primary

PERFORMANCE DATA

An engineering analysis including material and dimensional comparison of the SMV Scientific K-Wire and Pins and the predicate device was performed. The SMV Scientific K-Wire and Pins

are equivalent in physical dimensions and materials to the identified predicate devices. Testing, therefore, was not needed to demonstrate that the subject devices are substantially equivalent to the legally marketed predicate devices.

CONCLUSION

The similarity in indications for use and overall technological characteristics, and engineering analysis data lead to the conclusion that the SMV Scientific K-Wire and Pins are substantially equivalent to the predicate device.