October 16, 2019

A.M. Surgical, Inc.
Vincent Pascale
Chief Operations Officer
285 Middle Country Road, Suite 206
Smithtown, New York 11787

Re: K191771
Trade/Device Name: SECURE Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: July 2, 2019
Received: July 2, 2019

Dear Vincent Pascale:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

II. Indications for Use Statement

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 below.

510(k) Number *(if known)*
K191771

Device Name
SECURE Screw

Indications for Use *(Describe)*
The SECURE Screw is intended for fixation of intra-articular and extra-articular fractures and non-unions of small bones and small bone fragments; arthrodesis of small joints; bunionectomies and osteotomies, including scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, patella, ulnar styloid, capitellum, radial head and radial styloid.

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.

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

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FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

III. 510(k) Summary

K191771 SECURE Screw

I. SUBMITTER/OWNER

A.M. Surgical, Inc.
285 Middle Country Road, Suite 206
Smithtown, NY 11787

Establishment Registration: 2437731

Phone: 631-979-9777

Fax: 631-980-4369

Contact Person: Vin Pascale

Date Prepared: July 1, 2019

II. DEVICE

Tradename of Device: SECURE Screw
Common or Usual Name: Bone screw, fastener, fixation device
Classification Regulation: 21 CFR 888.3040 Screw, Fixation,
Bone Regulatory Class: II
Product Code: HWC
Special Controls or Device Specific Standards: N/A

III. PREDICATE DEVICE

The subject device is equivalent to the predicate K050636 Synthes 3.0mm headless compression screws.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The A.M. Surgical SECURE Screw is a stainless steel, cannulated, partially threaded, headless screw intended to be used for fracture fixation of small, long bones of the hands and feet. Screw threads provide compression to promote reunion of fracture fragments. The device is offered in five different lengths; 40mm, 45mm, 50mm, 55mm, and 60mm. All dimensions, excluding length, are the same among the different sizes. These varying lengths allow for personalized medical treatment of fractures geared toward each individual patient and different types of fractures. The device is manufactured out of a single piece of 316LVM (UNS-S31673) stainless steel, is provided sterile (via gamma radiation), and is not reusable or re-sterilizable. This device is intended for permanent implantation, but

can also be removed. To install and remove the device from a patient, the F543 compliant T8 hexalobe drive connection on the screw head is used in conjunction with a commercially available guide wire, drill bit, and driver.

V. INDICATIONS FOR USE

The SECURE Screw Fixation Device is intended for fixation of intra-articular and extra-articular fractures and non-unions of small bones and small bone fragments; arthrodesis of small joints; bunionectomies and osteotomies, including scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, patella, ulnar styloid, capitellum, radial head and radial styloid.

There are no differences between the SECURE System and the predicate with respect to indications and intended use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The general device description, intended use, indications for use, material, sterility, and single use configuration are the same between the SECURE Screw and the predicate device. The minor differences in the screw diameter and lengths offered do not affect the safety and efficacy of the device.

VII. PERFORMANCE DATA

To verify the design meets it functional and performance requirements, representative samples of the device meet biocompatibility, sterility and performance testing in accordance with the following industry standards.

- ISO 10993-1: Biological evaluation of medical devices
- ANSI/AAMI/ISO -11137-2: Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose
- ASTM F543-17: Standard Specification and Test Methods for Metallic Medical Bone Screws (Appendices 1, 2 and 3)

No clinical data were required or submitted in support of this submission.

VIII. CONCLUSIONS

The SECURE Screw has the same indications for use and nearly identical technological characteristics to the predicate device (K050636) previously cleared by the FDA. A.M. Surgical has concluded the SECURE Screw does not raise any new safety or effectiveness issues and is substantially equivalent to legally marketed bone screws that are in commercial distribution, and have been determined to be substantially equivalent to devices in commercial distribution, prior to May 28, 1976. This conclusion is based upon the devices' common indications for use, principles of operation, technology, materials and testing standards employed.