July 17, 2019

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

Re: K191345
Trade/Device Name: Pegasus System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: May 17, 2019
Received: May 20, 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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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 below.

510(k) Number *(if known)*
K191345

Device Name
Pegasus System

Indications for Use *(Describe)*

The Pegasus System is indicated for diagnostic and operative arthroscopic and endoscopic procedures to provide illumination and visualization of an interior cavity of the body through either a natural or surgical opening.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Pegasus System

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: May 17, 2019

II. DEVICE

Tradename of Device: Pegasus System
Common or Usual Name: Arthroscope, wireless endoscopic camera system
Classification Regulation: 888.1100 Arthroscope
Regulatory Class: II
Product Code: HRX
Special Cont***rols or Device Specific Standards: N/A***

III. PREDICATE ***DEVICE***

The subject device is equivalent to the predicate K162475 mi-eye 2.
No refer***ence devices were used in this submission.***

IV. DEVICE ***DESCRIPTION***

The Pegasus System is a portable, disposable, rigid, video camera enabled handheld probe paired with a wireless video receiver. It is powered by internal batteries encased in a plastic handpiece/handle. The distal tip of the stainless steel probe contains a camera and LED light source for visualization. The device is provided sterile and is intended for single patient use.

V. INDICATIONS FOR USE

The Pegasus System is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination and visualization of an interior cavity of the body through either a natural or surgical opening.

There are no differences between the Pegasus 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, visualization method, illumination method, field of view, energy source, video display, probe function, sterility, single use, biocompatibility and electrical safety are the same between the Pegasus System and the predicate device. The minor differences in the probe diameter and method of video transmission do not affect the safety and efficacy of the device. The predicate device has a flushing port and retractable needle design, which do not apply to the Pegasus system.

VII. PERFORMANCE DATA

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

- ISO 10993-1: Biological evaluation of medical devices
- IEC-60601-1: Medical Electrical Equipment
- EN-60601-1-2: Medical Electrical Equipment: General requirements for Basic Safety and Essential Performance. Collateral Standard. Electromagnetic Compatibility, requirements and tests.
- ISO-11135: Sterilization of Health Care Products. Ethylene Oxide. Requirements of development, Validation and Routine Control of a Sterilization Process for Medical Devices.
- ISO 10993-7, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals

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

VIII. CONCLUSIONS

The Pegasus System has the same indications for use and nearly identical technological characteristics to the predicate device (K162475) previously cleared by the FDA. A.M. Surgical has concluded the Pegasus System does not raise any new safety or effectiveness issues and is substantially equivalent to legally marketed arthroscopes 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.