DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 28, 2016

Mighty Oak Medical Inc.
Mr. Mark A. Wylie
Director of Quality and Regulatory
750 West Hampden Avenue, Suite 120
Englewood, Colorado 80110

Re: K162419
Trade/Device Name: FIREFLY® Pedicle Screw Navigation Guide
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: PQC
Dated: August 30, 2016
Received: August 30, 2016

Dear Mr. Wylie:

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" (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,

Mark N. Melkerson -S

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 below.

510(k) Number *(if known*

K162419

Device Name

FIREFLY® Pedicle Screw Navigation Guide

Indications for Use *(Describe)*

The FIREFLY® Pedicle Screw Navigation Guide can be used with any 510(k) cleared, legally marketed, pedicle screw spinal system (for its cleared indications for use) and its respective compatible components for non-cervical open, posterior spinal fixation procedures (T1-S2/ilium) intended for fusion, with the additional conditions listed below:

- *Pedicle screw's shank is straight along its longitudinal axis (i.e. not curved)*
- *Pedicle screw's major and minor thread diameters are centered about the longitudinal axis*
- *Pedicle screw's longitudinal axis matches the direction of insertion*
- *Pedicle screw is intended to be inserted into a pilot hole*
- *Pedicle screw's diameter is larger than the pilot hole created with FIREFLY®*
- *Patient's pedicle must be dimensionally adequate to accommodate a pedicle screw, as determined on preoperative scan*
- *Compatible pedicle screw spinal system instruments may be used with the FIREFLY® Pedicle Screw Navigation Guide*
    - *Pedicle sounding probes (a.k.a. feeler/ball-tip probes) may be used to confirm pedicle integrity*
    - *Only OEM pedicle screw spinal system taps specified in the Approved Patient-Specific Surgical Plan may be guided to tap pilot holes*
    - *All other pedicle screw spinal system components and accessories (including non-guided taps) are to be used, after removal of the FIREFLY® Pedicle Screw Navigation Guide, as directed by the pedicle screw spinal system's instructions for use*

This device is intended for single use only.

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.

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FIREFLY® Pedicle Screw Navigation Guide

Submitter:

Mighty Oak Medical Inc.
750 W. Hampden Ave., Suite 120
Englewood, CO 80110
(720) 398-9703

Contact: Mark A. Wylie, Director of Quality and Regulatory

Date Prepared: 10/26/2016

Device

Trade Name: FIREFLY® Pedicle Screw Navigation Guide

Common Name: Pedicle Screw Placement Guide

Device Classification: Class II

Regulation, Name: 21 CFR 888.3070, Pedicle screw spinal system

Device Product Code: PQC

Predicate Device(s):

FIREFLY® Pedicle Screw Navigation Guide

Primary Predicate:

K143222 (S.E. 12/11/2015)

Description

The FIREFLY® Pedicle Screw Navigation Guide is intended to assist in the accurate placement of pedicle screws. It consists of single-use components designed for treatment of a specific patient as well as reusable non-patient-specific components.

The FIREFLY® Pedicle Screw Navigation Guide uses Patient-Specific Pedicle Screw Guides that fit on the patient's anatomy to guide surgical instruments in line with trajectories chosen presurgically, by the surgeon, based on the patient's CT imaging data. Navigation guides are intended to guide instruments to create pilot holes in the pedicles for placing pedicle screws following the Approved Patient-Specific Surgical Plan.

Patient-Specific Bone Models may also be provided.

The purpose of this traditional 510(k) is to expand the FIREFLY® indications for use to allow compatibility with all pedicle screw systems (for their cleared indications for use) meeting certain criteria and use at an additional spinal level. The FIREFLY® design is the same as was originally cleared in **K143222**.

Indications for Use

The FIREFLY® Pedicle Screw Navigation Guide can be used with any 510(k) cleared, legally marketed, pedicle screw spinal system (for its cleared indications for use) and its respective compatible components for non-cervical open, posterior spinal fixation procedures (T1-S2/ilium) intended for fusion, with the additional conditions listed below:

- *Pedicle screw's shank is straight along its longitudinal axis (i.e. not curved)*
- *Pedicle screw's major and minor thread diameters are centered about the longitudinal axis*
- *Pedicle screw's longitudinal axis matches the direction of insertion*
- *Pedicle screw is intended to be inserted into a pilot hole*
- *Pedicle screw's diameter is larger than the pilot hole created with FIREFLY®*
- *Patient's pedicle must be dimensionally adequate to accommodate a pedicle screw, as determined on preoperative scan*
- *Compatible pedicle screw spinal system instruments may be used with the FIREFLY® Pedicle Screw Navigation Guide*
    - *Pedicle sounding probes (a.k.a. feeler/ball-tip probes) may be used to confirm pedicle integrity*
    - *Only OEM pedicle screw spinal system taps specified in the Approved Patient-Specific Surgical Plan may be guided to tap pilot holes*
    - *All other pedicle screw spinal system components and accessories (including non-guided taps) are to be used, after removal of the FIREFLY® Pedicle Screw Navigation Guide, as directed by the pedicle screw spinal system's instructions for use*

This device is intended for single use only.

Materials

The patient-contacting components of the FIREFLY® Pedicle Screw Navigation Guide are manufactured from titanium alloy (ASTM F136), various stainless steels (ASTM F899), and epoxy resin (Accura ABS White SL 7810).

Performance Data

Additional cadaveric accuracy testing of the FIREFLY® Pedicle Screw Navigation Guide was performed. The results demonstrated that the acceptance criteria were met and that the FIREFLY® Pedicle Screw Navigation Guide's performance is adequate to perform as intended.

Technological Characteristics

The subject FIREFLY® Pedicle Screw Navigation Guide possesses the same technological characteristics as the predicate device. These include:

- Performance
- Manufacturing process
- Sterilization
- Biocompatible materials
- Basic design

Technological characteristics which are different have been supported with descriptive information and/or performance data. Therefore the fundamental scientific technology of FIREFLY® is the same as the previously cleared device.

Conclusion

The FIREFLY® Pedicle Screw Navigation Guide possesses the same intended use and technological characteristics as the predicate device. Therefore the FIREFLY® Pedicle Screw Navigation Guide is substantially equivalent for its intended use.