July 24, 2018

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

Re: K181399
Trade/Device Name: FIREFLY® Pedicle Screw Navigation Guide
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: PQC
Dated: May 29, 2018
Received: May 29, 2018

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 Part 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.

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,

Ronald P. Jean -S

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: January 31, 2017

See PRA Statement below.

510(k) Number *(if known*

K181399

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/S2AI and 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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510(K) SUMMARY

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, VP of Quality and Regulatory

Date Prepared: 01June 2018

Device

Trade Name: FIREFLY® Pedicle Screw Navigation Guide

Common Name: Pedicle Screw Placement Guide

Device Classification: Class II

Regulation, Name: 21 CFR 888.3070, Thoracolumbosacral pedicle screw system

Device Product Code: PQC

Predicate Device(s):

FIREFLY® Pedicle Screw Navigation Guide

Primary Predicate:

K162419 (S.E. 10/28/2016)

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 use at an additional spinal level. The FIREFLY® design is the same as was originally cleared in **K143222** and **K162419**.

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/S2AI and ilium) intended for fusion, with the additional conditions listed below:

- *Pedicle screw's shank is straight along its longitudinal axis (i.e. not curved)*
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- *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.