October 26, 2022

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

Re: K220132
Trade/Device Name: FIREFLY® Cervical Navigation Guide
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: QSD
Dated: September 22, 2022
Received: September 26, 2022

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. 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,

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220132

Device Name
FIREFLY® Cervical Navigation Guide

Indications for Use *(Describe)*

The FIREFLY® Cervical Navigation Guide system is intended to provide mechanical guidance for the preparation and drilling of pilot holes for the placement of posterior cervical screws in the cervical spine (C1-C7) and the upper thoracic spine (T1-T3). Pilot holes are created using the FIREFLY® Cervical Navigation Guide in the pedicles (C2-T3), Pars (C2), or lateral masses (C1) during open, posterior spinal fixation procedures, on skeletally mature patients, that are intended for fusion. The patient's pedicles, pars, or lateral masses must be dimensionally adequate to safely accommodate a posterior cervical screw, as determined on a preoperative CT/CTA scan.

The FIREFLY® Cervical Navigation Guide system is compatible with FDA cleared, legally marketed, posterior cervical screw systems (and their respective compatible components) that are specified in the precautions. Pedicle sounding probes (a.k.a. feeler/ball-tip probes) may be used to confirm each pedicle's integrity. Only qualified compatible OEM posterior cervical screw system taps may be used to visually guide the tapping of pilot holes. All other posterior cervical screw system components and accessories (including non-visually guided taps) are to be used, after removal of the FIREFLY® Cervical Navigation Guide, as directed by the posterior cervical screw system's instructions for use.

The FIREFLY® Cervical Navigation Guide system is only compatible with Power drill consoles systems (attachments and burs) listed in the precautions.

This system (guide, bone model, drill bit, and depth stop) are 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.

510(K) SUMMARY

Mighty Oak Medical

FIREFLY® Cervical 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: 14JAN2022

Device

Trade Name: FIREFLY® Cervical Navigation Guide
Common Name: Posterior Cervical Screw Placement Guide
Device Classification: Class II
Regulation, Name: 21 CFR 888.3075, Posterior Cervical Screw System
Device Product Code: QSD

Type of 510(k)

Original Submission: Traditional

Predicate Device(s):

FIREFLY® Cervical Navigation Guide

510(k)	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K153631	NKG	Virage OCT Spinal System	Zimmer
Reference Device			
K181399	PQC	FIREFLY Pedicle Screw Navigation Guide	Mighty Oak Medical

Description

The FIREFLY® Cervical Navigation Guide is intended to assist in the accurate placement of posterior cervical screws. It consists of single-use components designed for treatment of a specific patient.

The FIREFLY® Cervical Navigation Guide uses Patient-Specific Cervical 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/CTA imaging data. Navigation guides are intended to guide instruments to create pilot holes in the pedicles (C2-T3), Pars (C2), or lateral masses (C1) for placing screws following the Approved Patient-Specific Surgical Plan.

Patient-Specific Bone Models are also provided.

The primary purpose of the 510(k) is to receive clearance from the Food and Drug Administration ("FDA" or "the Agency") regarding the above requests.

The FIREFLY® Cervical Navigation Guide design is the similar to the originally cleared FIREFLY® Pedicle Screw Navigation Guide in **K143222, K162419, and K181399**.

Indications for Use

The FIREFLY® Cervical Navigation Guide system is intended to provide mechanical guidance for the preparation and drilling of pilot holes for the placement of posterior cervical screws in the cervical spine (C1-C7) and the upper thoracic spine (T1-T3). Pilot holes are created using the FIREFLY® Cervical Navigation Guide in the pedicles (C2-T3), Pars (C2), or lateral masses (C1) during open, posterior spinal fixation procedures, on skeletally mature patients, that are intended for fusion. The patient's pedicles, pars, or lateral masses must be dimensionally adequate to safely accommodate a posterior cervical screw, as determined on a preoperative CT/CTA scan.

The FIREFLY® Cervical Navigation Guide system is compatible with FDA cleared, legally marketed, posterior cervical screw systems (and their respective compatible components) that are specified in the precautions. Pedicle sounding probes (a.k.a. feeler/ball-tip probes) may be used to confirm each pedicle's integrity. Only qualified compatible OEM posterior cervical screw system taps may be used to visually guide the tapping of pilot holes. All other posterior cervical screw system components and accessories (including non-visually guided taps) are to be used, after removal of the FIREFLY® Cervical Navigation Guide, as directed by the posterior cervical screw system's instructions for use.

The FIREFLY® Cervical Navigation Guide system is only compatible with Power drill consoles systems (attachments and burs) listed in the precautions.

This system (guide, bone model, drill bit, and depth stop) are intended for single use only.

Materials

The patient-contacting components of the FIREFLY® Cervical Navigation Guide are manufactured from a polymer powder for use in additive manufacturing (HP High Reusability PA12).

Performance Data

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

Technological Characteristics

The subject FIREFLY® Cervical Navigation Guide possesses the same technological characteristics as the predicate and reference devices. These include:

- Creation of a pilot hole for insertion of a posterior cervical screw
- 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® Cervical Navigation Guide possesses the same intended use and technological characteristics as the predicate devices. Therefore the FIREFLY® Cervical Navigation Guide is substantially equivalent for its intended use.