



February 25, 2026

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

Re: K253472

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: October 6, 2025
Received: October 10, 2025

Dear Mark 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

EILEEN
CADEL-S for

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K253472

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Please provide the device trade name(s).

?

FIREFLY® Pedicle Screw Navigation Guide

Please provide your Indications for Use below.

?

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/S2Al 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
 - o Pedicle sounding probes (a.k.a. feeler/ball-tip probes) may be used to confirm pedicle integrity
 - o Only OEM pedicle screw spinal system taps specified in the Approved Patient-Specific Surgical Plan may be guided to tap pilot holes
 - o 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.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)
 Over-The-Counter Use (21 CFR 801 Subpart C)

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510(K) SUMMARY

FIREFLY® Pedicle Screw Navigation Guide

Submitter:

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

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

Date Prepared: 06OCT2025

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

Type of 510(k)

Original Submission: Traditional.

Predicate Device(s):

510(k)	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K181399	PQC	FIREFLY® Pedicle Screw Navigation Guide	Mighty Oak Medical

Introduction

This 510(k) filing seeks to expand the FIREFLY® indications for use with MRI-derived synthetic CT scans as an input. The FIREFLY® design is the same as was originally cleared in K143222, K162419, and K181399.

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 or MRI-Derived Synthetic CT data.

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 or MRI-Derived Synthetic 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.

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/S2Al 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.

Materials

The material used to manufacture patient-specific components is an epoxy resin for use in stereolithography systems or polymer powder for use in multi-jet fusion systems. Patient contacting materials used for non-patient-specific components are manufactured in accordance with ASTM F899 or F136.

Performance Data

Quantitative and Qualitative validations were completed to demonstrate that MRI-Derived synthetic CT inputs generate equivalent FIREFLY Pedicle Screw Navigation Guide system components when compared to CT scan inputs, including: Segmentation Output Quantitative Comparison, Presurgical Plan Qualitative Comparison, and MRI-derived sCT Qualification. 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.

Substantial Equivalence Discussion

The table below provides a descriptive comparison of the similarities and differences for the subject and predicate device.

Table 1 - Comparison of Devices

Device→ Features↓	FIREFLY Pedicle Screw Navigation Guide (This Submission)	FIREFLY Pedicle Screw Navigation Guide	Equivalency
Premarket notification	K253472 (Current Submission)	K181399	N/A
Manufacturer	Mighty Oak Medical	Mighty Oak Medical	No change
Device Description	<p>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.</p> <p>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 preoperative 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.</p> <p>Patient-Specific Bone Models may also be provided.</p>	<p>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.</p> <p>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.</p> <p>Patient-Specific Bone Models may also be provided.</p>	Addition of MRI-Derived Synthetic CT imaging data as an input

Device→ Features↓	FIREFLY Pedicle Screw Navigation Guide (This Submission)	FIREFLY Pedicle Screw Navigation Guide	Equivalency
Indications for Use Statement	<p>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/S2Al and ilium) intended for fusion, with the additional conditions listed below:</p> <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> ○ 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 <p>This device is intended for single use only.</p>	<p>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/S2Al and ilium) intended for fusion, with the additional conditions listed below:</p> <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> ○ 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 <p>This device is intended for single use only.</p>	No change
General intended use	<p>A pedicle screw placement guide is intended to be used as a surgical instrument to assist in the intra-operative placement of pedicle screws that are used to anchor pedicle screw spinal systems onto the posterior elements of the spine. The device utilizes anatomic landmarks that are identifiable on preoperative imaging scans.</p>	<p>A pedicle screw placement guide is intended to be used as a surgical instrument to assist in the intra-operative placement of pedicle screws that are used to anchor pedicle screw spinal systems onto the posterior elements of the spine. The device utilizes anatomic landmarks that are identifiable on CT imaging scans.</p>	Update imaging scan language to be applicable to CT or MRI-Derived Synthetic CT imaging data
Product Classification	Pedicle Screw Placement Guide	Pedicle Screw Placement Guide	No change
Regulatory Class	Class II	Class II	No change
Product Code	PQC	PQC	No change

Device→ Features↓	FIREFLY Pedicle Screw Navigation Guide (This Submission)	FIREFLY Pedicle Screw Navigation Guide	Equivalency
Anatomic location	Posterior Spine (T1-S2/S2AI and ilium)	Posterior Spine (T1-S2/S2AI and ilium)	No change
Technological characteristics	Assists in placement of any pedicle screws that meet conditions specified in the indications for use. All Guides T1-S2/S2AI and ilium are included and remain unchanged from K181399 as it relates to form, fit and function.	Assists in placement of any pedicle screws that meet conditions specified in the indications for use.	No change
Manufacturing process	Additive manufacturing	Additive manufacturing	No change
Basic design	Patient-specific surgical guide	Patient-specific surgical guide	No change
Contact duration	Limited (< 24 hours)	Limited (< 24 hours)	No change
Sterilization	Non-sterile	Non-sterile	No change
Method of use	Pedicle preparation for pedicle screw placement	Pedicle preparation for pedicle screw placement	No change
Image Acquisition Modality	CT Scan and MRI-Derived synthetic CT Scan	CT Scan	Addition of MRI-Derived Synthetic CT imaging data as an input

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