



Flow-FX, LLC
% Hollace Rhodes
Vice President, Orthopedic Regulatory Affairs
Mcra, LLC
803 7th Street NW
3rd Floor
Washington, District of Columbia 20001

February 5, 2024

Re: K234075
Trade/Device Name: Flow-Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: December 21, 2023
Received: January 10, 2024

Dear Hollace Rhodes:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 systems (QS) regulation (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.

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,

Farzana
Sharmin -S

Digitally signed by
Farzana Sharmin -S
Date: 2024.02.05
12:04:47 -05'00'

Farzana Sharmin, PhD
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K234075

Device Name

Flow-Nail

Indications for Use (Describe)

The Flow-Nail is intended to treat stable and unstable proximal fractures of the femur including pertrochanteric, intertrochanteric, and high subtrochanteric fractures and combinations of these fractures. The Flow-Nail can also be used to deliver injectable bone void fillers to a surgical site.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"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

Manufacturer: Flow-FX, LLC
9301 West 191st Street
Mokena, Illinois 60448
815.531.4424

Contact: Patrick J. Sweeney, MD
Chief Executive Officer

Prepared by: MCRA, LLC
803 7th Street, NW, 3rd Floor
Washington, DC 20001
Office: 202.552.5800

Date Prepared: February 2, 2024

Device Trade Name: Flow-Nail

Common Name: Trochanteric Nail System

Classification: 21 CFR 888.3020, Intramedullary fixation rod

Class: II

Product Code: HSB

Indications for Use:

The Flow-Nail is intended to treat stable and unstable proximal fractures of the femur including pertrochanteric, intertrochanteric, and high subtrochanteric fractures and combinations of these fractures. The Flow-Nail can also be used to deliver injectable bone void fillers to a surgical site.

Device Description:

The Flow-Nail is a dynamic compression trochanteric nail system and includes an intramedullary nail, a fenestrated lag screw, anti-rotation screw, cortical screws, a cap and accompanying surgical instruments. The Flow-Nail components are made of titanium alloy (Ti-6Al-4V) conforming to ASTM F136. The purpose of this Special 510(k) is to add the 10mm IM Nail to the Flow-Nail System. The IM Nail (10mm) is manufactured from Ti-6Al-4V per ASTM F136. The components are provided non-sterile, for single use, by prescription only.

Primary Predicate:

Flow-FX's Flow-Nail (K221115); 21 CFR 888.3020; Class II; HSB

The subject and predicate Flow-Nail devices are trochanteric nail systems which include an intramedullary nail, a fenestrated lag screw, anti-rotation screw, cortical screws, a cap and accompanying surgical instruments. All Flow-Nail components are made of titanium alloy (Ti-6Al-4V) conforming to ASTM F136.

Reference Device:

Zimmer Natural Nail System Cephalomedullary Nails (K231114); 21 CFR 888.3020; Class II; HSB

Performance Testing & Engineering Analysis:

- Compression bending strength – dynamic testing per ASTM F384
- Compression bending strength – static testing per ASTM F384
- Engineering analysis to address ASTM F1264 loading

Results of non-clinical performance and analyses demonstrate that the 10mm IM Nail Flow-Nail is safe and effective for its intended use.

Substantial Equivalence Conclusion:

Substantial equivalence of subject device (10mm IM Nail) to the predicate Flow-Nail device is based on the following:

- Both devices have the same intended use.
- Both devices operate using the same fundamental scientific technology.
- Both devices share the same functional and technological characteristics via the same operational principles.

Evaluation of the associated risks do not raise different questions of safety and effectiveness. Performance data referenced in this 510(k) submission demonstrate that the subject Flow-Nail 10mm IM Nail (10mm distal diameter) is safe and effective for its intended use and is substantially equivalent to Flow-Nail.