May 13, 2022

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

Re: K221115
Trade/Device Name: Flow-Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: April 15, 2022
Received: April 15, 2022

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 (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,

Lixin Liu, Ph.D.
Acting 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

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)*
K221115

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.

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510(k) Summary

Manufacturer: Flow-FX, LLC
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815.531.4424

Contact: Patrick J. Sweeney, MD
Chief Executive Officer
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Prepared By: MCRA, LLC
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Washington, DC 20001
Phone: 202.552.5800

Date Prepared: May 13, 2022

Device Trade Name: Flow-Nail

Common Name: Intramedullary Fixation Rod

Classification: 21 CFR 888.3020

Class: 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 Flow-Nail with Laglock to the Flow-Nail System. The components are provided non-sterile, for single use, by prescription only.

Predicate Device
Flow-FX's Flow-Nail (K140601); 21 CFR 888.3020; Class II

Substantial Equivalence Discussion
The subject Flow-Nail with Laglock is substantially equivalent to the predicate Flow-Nail (K140601) with respect to indications, material, design, function, and performance. The information summarized in the Design Control Activities Summary demonstrates that the Flow-Nail with Laglock met the pre-determined acceptance criteria for the verification activities.

Non-Clinical Performance Data
Performance testing included:

- Compression Bending Strength – Dynamic per ASTM F384
- Compression Bending Strength – Static per ASTM F384

Results of non-clinical performance and analyses demonstrate that the Flow-Nail with Laglock is as safe, as effective, and performs as well as the predicate device.

Substantial Equivalence Conclusion
Substantial equivalence of Flow-Nail with Laglock 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 similar functional and technological characteristics via similar operational principles.

Evaluation of the risk and performance data referenced in this 510(k) submission demonstrate that the subject Flow-Nail with Laglock is as safe and effective for its intended use and is substantially equivalent to Flow-Nail.