510(k) Summary

JUL 0 2 2014

Device Trade Name: Flow-Nail

Manufacturer:
Flow-FX, LLC
19110 Darvin Drive
Mokena, Illinois 60448
708.390.2290

Prepared by:
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
202.552.5800

Date Prepared: June 4, 2014

Common Name: Intramedullary Fixation Rod

Classification: 21 CFR 888.3020

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 sliding 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.

Predicate Devices:
The Flow-Nail was shown to be substantially equivalent to the Zimmer Natural Nail System (K120715 and K091566), Stryker Gamma 3 Nail System (K032244), and AOS Trochanteric Nail (K103533 and K021008). The Flow-Nail is compatible for use with injectable BVFs.

Substantial Equivalence:

The table below summarizes the substantial equivalence of the Flow-Nail to predicate devices with respect to its intended use, design, materials, available sizes, mechanical performance, and ability to deliver BVF to a defect site.

	Subject Device	**Predicates**		
	Flow-Nail	Zimmer Natural Nail	Stryker Gamma 3 Nail System	AOS Trochanteric Nail System (K021008)
Intended Use	Intended for temporary fracture fixation and stabilization of the bone.			
Indications for Use	The FlowNail 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.	Indications for the use of the Cephalomedullary nails include: - Compound and simple shaft fractures - Proximal, metaphyseal and distal shaft fractures - Segmental fractures - Comminuted fractures - Fractures involving osteopenic and osteoporotic bone - Pathological fractures - Fractures with bone loss - Pseudoarthrosis, non-union, mal-union and delayed union - Periprosthetic fractures - Surgically created defects such as osteotomies - Intertrochanteric and subtrochanteric fractures	The intended use of the subject Trochanteric Gamma 3 Nail is identical to that of the predicate Trochanteric Dyax and Gamma Nails. The product is intended for use in stabilizing various types of intertrochanteric fractures of the femur.	The AOS Trochanteric 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.
Components	IM Nail; Lag Screw	IM Nail; Lag Screw	IM Nail: Lag Screw	IM Nail; Lag Screw
Materials	Titanium Alloy	Titanium Alloy	Titanium Alloy	Titanium Alloy
Nail Sizes	Within predicate range	A range of sizes to accommodate various patient anatomies	A range of sizes to accommodate various patient anatomies	A range of sizes to accommodate various patient anatomies
Lag Screw Sizes	Within predicate range	A range of lengths to accommodate various patient anatomies	A range of lengths to accommodate various patient anatomies	A range of lengths to accommodate various patient anatomies
Mechanical Performance	Mechanical testing demonstrates the substantial equivalence of the Flow-Nail relative to the identified predicates when subjected to static and dynamic compression bending loads.			
BVF Delivery	Yes	No	No	No
BVF Delivery System	The qualification testing (i.e., Injectability Testing, Experimental Void Fill Imaging Studies, Static Extraction Torque, BVF Property characterization), was performed with ETEX Beta-bsm and CarriGen (K062630, K072355, K090242, K101557).			

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 2, 2014

Flow-FX, LLC
% Ms. Michelle McDonough
Senior Associate, Regulatory and Clinical Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street Northwest, 12th Floor
Washington, District of Columbia 20005

Re: K140601
Trade/Device Name: Flow-Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: June 4, 2014
Received: June 5, 2014

Dear Ms. McDonough:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Laurence D. Coyne -A

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K140601

Device Name: Flow-Nail

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.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices

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