



Food and Drug Administration
10903 New Hampshire Avenue
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InnoVision, Incorporated
% Ms. Hollace Saas Rhodes
Director, Orthopedic Regulatory Affairs
1331 H Street NW, 12th Floor
Washington, District of Columbia 20005

July 24, 2015

Re: K151146
Trade/Device Name: N-Force Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: April 28, 2015
Received: April 29, 2015

Dear Ms. 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. 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,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K151146

Device Name

N-Force Fixation System

Indications for Use (Describe)

The N-Force Fixation System is intended for the fixation of bone fractures and bone reconstructions. When used for these indications, the N-Force Fixation System 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: InnoVision, Inc.
1975 Nonconnah Boulevard
Memphis, TN 38132

Device Trade Name: N-Force Fixation System

Common Name: Smooth or threaded metallic bone fixation fastener

Date Prepared: April 28, 2015

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

Device Trade Name: N-Force Fixation System

Classification: 21 CFR 888.3040, Smooth or threaded metallic bone fixation fastener

Class: II

Product Code: HWC

Indications for Use:

The N-Force Fixation System is intended for the fixation of bone fractures and bone reconstructions. When used for these indications, the N-Force Fixation System can also be used to deliver injectable bone void fillers to a surgical site.

Device Description:

The N-Force Fixation System includes fully and partially cannulated screws in various diameters and lengths, in both fenestrated and non-fenestrated options. The system also includes washers and accompanying instruments.

The N-Force Fixation System implants are made of titanium alloy.

Predicate Device:

The N-Force Fixation System is substantially equivalent to the predicate N-Force Fixation System (K102528, K132244) with respect to indications, design, function, performance, materials and its ability to deliver BVFs to a surgical site.

Substantial Equivalence:

Testing performed on the N-Force Screw indicates that it is substantially equivalent to the predicate devices. Mechanical testing of the screw included static three-point bending, torsion, axial pull-out, and insertion torque. Bone void filler injection testing included injectability, experimental void fill imaging, relative paste hardness, X-Ray diffraction, and static extraction torque.