K053623

JUL 12 2006

Section 1 510(k) Summary

SUBMITTED ON BEHALF OF:	**N Spine, Inc.** 6244 Ferris Square, Suite B San Diego, CA 92121-3239
Telephone:	(858) 452-1266
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by:	Elaine Duncan, M.S.M.E., RAC President, Paladin Medical, Inc. PO Box 560 Stillwater, MN 55082
Telephone:	715-549-6035
Fax:	715-549-5380
CONTACT PERSON:	**Elaine Duncan**
DATE PREPARED:	December 16, 2005
TRADE NAME:	NFix Fusion System
COMMON NAME:	Spinal System, Fusion
CLASSIFICATION NAME	Posterior Spinal Fusion System with solid rod and pedicle screws
REGULATION	21 CFR 888.3070
Regulatory Class	Class 2
Device Panel and Product Code:	Orthopedic Panel – Product Code: MNH
SUBSTANTIALLY EQUIVALENT TO:	Moss Miami Spinal System

DESCRIPTION of the DEVICE:
The NFix Fusion System consists of four or more pedicle screws and two NFix solid rods in a symmetric, bilateral arrangement. The pedicle screws are placed axially in the pedicles with two screws in the cephalad position and two screws in the caudad position. The NFix solid rods are secured in the heads of the pedicle screws so that fixed stabilization is provided between the cephalad and caudad vertebrae. Crosslinks can be used if additional stabilization is necessary.

INDICATIONS FOR USE:
The NFix Fusion System is intended for posterior, noncervical, pedicle fixation in order to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine, including degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis). In addition, when used as a pedicle screw fixation system, the NFix Fusion System is intended for skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra, who are receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 and below), with removal of the implants after the attainment of solid fusion.

SUMMARY OF TESTING:
The technological characteristics of the NFix Fusion System are similar to the Moss Miami Spinal System, manufactured by DePuy Inc. Establishment of similarities is based upon similarities of intended use, design and mechanical performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2006

N-Spine, Inc.
% Paladin Medical, Inc.
Ms. Elaine Duncan
President
PO Box 560
Stillwater, Minnesota 55082

Re: K053623
Trade/Device Name: NFix Fusion System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH
Dated: May 30, 2006
Received: May 31, 2006

Dear Ms. Duncan:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Melkerson for

Mark N. Melkerson
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K053623

Indications for Use

510(k) Number (if known):

Device Name: NFix Fusion System

Indications For Use:

NFix Indications for Use:

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In addition, when used as a pedicle screw fixation system, the NFix Fusion System is intended for skeletally mature with severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra, who are receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 and below), with removal of the implants after the attainment of solid fusion.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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