K061774

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5.0 510(k) SUMMARY

In accordance with Title 21 of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safety and effectiveness information is provided:

5.1 Submitted By

N Spine, Inc.
6244 Ferris Square, Suite B, San Diego, California 92121-3239
Telephone: (858) 452-1266

Contact: R. Stephen Reitzler, Authorized Regulatory Agent

Date Prepared: June 19, 2006

5.2 Device Name

Trade or Proprietary Names: *N Fix II* Pedicle Screw System

Common or Usual Name: Pedicle Screw System

Classification Name: Pedicle Screw Spinal System

Product Code: NQP

Classification: 21 CFR, §888.3070

5.3 Predicate Devices

The subject device is substantially equivalent to the following predicate devices:

- *Isobar* System (Scient'x USA; K990118 to K020245)
- *Moss Miami* System (DePuy Acromed; K950697 to K030383)
- *Synergy* System (Interpore Cross; K950099 to K011437)
- *Optima* System (U & I Corp.; K024096)
- *N Fix* System (N Spine; K053623)
- *DYNESYS*® System (Centerpulse Spine-Tech; K031511)

5.4 Device Description

The subject *N Fix II* device is a posterior instrumentation system consisting of both pedicle screws and connecting rods. Screws are of polyaxial top-loading design, are composed of titanium 6Al-4V ELI alloy, and are available in 5.5mm, 6.5mm, and 7.5mm diameters, in lengths ranging from 35mm to 60mm. Rods are composed of titanium 6Al-4V ELI alloy and synthetic polycarbonate urethane (PCU) polymer, are 6.0mm in diameter, and are available in lengths from 40mm to 200 mm.

5.5 Intended Use

Like other pedicle screw systems of its type, when used as a pedicle screw fixation system in skeletally mature patients, the *N Fix II* System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, kyphosis, and failed previous fusion (pseudoarthrosis).

In addition, when used as a pedicle screw fixation system, the *N Fix II* System is indicated in patients who are receiving fusions with autogenous graft only; who are having the device fixed or attached to the lumbar or sacral spine; and who are having the device removed after the development of a solid fusion mass.

5.6 Comparison to Predicate Devices

Testing and other comparisons have established that the subject *N Fix II* pedicle screw system is substantially equivalent in design, materials, indications and intended use, packaging, labeling, and performance to other predicate devices of the type currently marketed in the U.S.

5.7 Summary of Non-Clinical Tests

Nonclinical tests, including those conducted in accordance with recognized standards, have demonstrated the substantial equivalence of the subject device to commercially-available predicates in terms of performance.

5.8 Summary of Clinical Tests

(Not applicable)

5.9 Conclusions of Non-Clinical and Clinical Tests

The results of all testing demonstrated the substantial equivalence of the subject devices to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NSpine
% R. Stephen Reitzler, RAC
Regulatory Agent
13221 Maricotte Place
San Diego, California 92130

DEC 13 2006

Re: K061774
Trade Name: NFIX II Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Posterior metal/polymer spinal system
Regulatory Class: Class II
Product Code: NQP
Dated: October 30, 2006
Received: October 31, 2006

Dear Mr. Reitzler:

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

"The safety and effectiveness of this device for use in the treatment of spinal stabilization without fusion have not been established."

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

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

510(k) premarket notification if the limitation statement described above is added to your labeling.

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); 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 information about the application of other labeling requirements to your device (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" (21 CFR 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,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061774

Device Names: *N Fix II Pedicle Screw System*

Indications for Use:

When used as a pedicle screw fixation system in skeletally mature patients, the N Fix II *System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, kyphosis, and failed previous fusion (pseudoarthrosis).*

In addition, when used as a pedicle screw fixation system, the N Fix II *System is indicated in patients:*

- *who are receiving fusions with autogenous graft only;*
- *who are having the device fixed or attached to the lumbar or sacral spine;*
- *who are having the device removed after the development of a solid fusion mass.*

Prescription Use X (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)

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

510(k) Number K061774