K033512

Procyon Spinal System

510(k) Application

JUN 0 3 2004

B. PREMARKET NOTIFICATION 510(K) SUMMARY

Company:

NAS Medical Technologies, Inc.
9191 Towne Centre Dr., Suite 395
San Diego, CA 92122
Phone: (858) 452-5589
Fax: (858) 777-5790

Contact:

Makoto Nonaka, M.D., Ph.D.

Proposed Proprietary Trade Name:

Procyon Spinal System

Classification Name:

Spondylolisthesis spinal fixation device system
Pedicle screw system

FDA Product Code Classification:

MNI: 888. 3070, MNH: 888.3070

Device Description:

The Procyon Spinal System consists of polyaxial screws, rods, and connecting components. The components are fabricated from titanium alloy (ASTM F-136).

Intended Use:

When used as a pedicle screw fixation system in the non-cervical spine of skeletally mature patients, the Procyon Spinal System is intended for 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: 1) degenerative spondylolisthesis with objective evidence of neurological impairment, 2) fracture, 3) dislocation, 4) scoliosis, 5) kypohsis, 6) spinal tumor and 7) failed previous fusion (pseudoarthrosis).

In addition, when used as a pedicle screw fixation system, the Procyon Spinal System is intended for skeletally mature patients: 1) having severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra, 2) who are receiving fusion by autogenous bone graft only; 3) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and 4) who are having the device removed after the development of a solid fusion mass.

Predicate Devices:

TSRH Spinal System (K030285)
MONARCII Spine System (K021335)

Performance Data:

Performance data were submitted to characterize the Procyon Spinal System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 0 3 2004

Makoto Nonaka, M.D., Ph.D.
NAS Medical Technologies, Inc.
9191 Towne Centre Drive, Suite 395
San Diego, California 92122

Re: K033512
Trade Name: Procyon Spinal System
Regulation Number: 21 CFR 888.3070 (b) (1)
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: March 22, 2004
Received: March 23, 2004

Dear Dr. Nonaka:

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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Procyon Spinal System

510(k) Application

TAB 5. Labeling

A. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K033512

Device Name: Procyon Spinal System

Indications for Use:

When used as a pedicle screw fixation system in the non-cervical spine of skeletally mature patients, the Procyon Spinal System is intended for 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: 1) degenerative spondylolisthesis with objective evidence of neurological impairment, 2) fracture, 3) dislocation, 4) scoliosis, 5) kypohsis, 6) spinal tumor and 7) failed previous fusion (pseudoarthrosis).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-The-Counter Use _____

Miriam C. Provost

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

510(k) Number K033512