K090424

510(k) Summary

MAY 14 2009

Submitted on behalf of:
BK MEDITECH Co., Ltd.
215-5 Yodang-Li, Yanggam-Myun, Hwasung-Si,
Kyunggi-Do, Republic of Korea

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: **February 16, 2009**

TRADE NAME: **DVX 5.5 Spinal System**
COMMON NAME: Spinal System, Fusion
CLASSIFICATION NAME: Posterior Spinal Fusion System with solid rod and pedicle screws
REGULATION and CLASS 21 CFR § 888.3070, Class 2
PANEL and PRO CODE: Orthopedic; MNH

SUBSTANTIALLY EQUIVALENT TO: The DVX 5.5 Spine System is substantially equivalent to the original DVX Spine System cleared under K080876. Because of the difference in size for the 5.5 System, ASTM 1717-04 was repeated. There are no other substantial differences between the subject devices and the predicate devices and thus no differences which could affect safety or efficacy.

DESCRIPTION of the DEVICE: The DVX 5.5 Spine System DVX5.5 Spine System (like the predicate The DVX Spine System) consists of four or more pedicle screws and two 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 rods are secured in the heads of the pedicle screws so that fixed stabilization is provided between the cephalad and caudad vertebrae. Cross-links can be used if additional stabilization is necessary. The DVX5.5 Spine System (See Figure 1) is made of components for fixation of the spine: multi-axial pedicle screws, locking cap, rod and cross-link . The materials, sterilization and packaging are the same as those in DVX Spine System, the predicate.

INDICATIONS FOR USE: The DVX 5.5 Spine System has the same indication for use and same intended use as the predicate DVX Spine System, cleared by this sponsor (BK Meditech Co., Ltd.) The indication is:

The DVX 5.5 Spine 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 DVX Spine 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.

BASIS for SUBSTANTIAL EQUIVALENCE: DVX 5.5 Spine System is a small version of the predicate DVX Spine System previously cleared under K080876. Testing to ASTM 1717-04 confirms the smaller system also meets basic performance requirements for spinal fusion systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2009

BK Meditech Company, Ltd.
% Paladin Medical
Ms. Elaine Duncan, M.S.M.E, RAC
President
P.O. Box 560
Stillwater, Minnesota 55082

Re: K090424
Trade/Device Name: DVX 5.5 Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNH
Dated: February 17, 2009
Received: February 19, 2009

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

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

Enclosure

Indications for Use

510(k) Number (if known): K090424

Device Name:

Indications For Use:

The DVX 5.5 Spine 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 DVX Spine 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.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090424