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510(k) Summary

Submitted on behalf of:

Company Name: **BK Meditech Co, Ltd**
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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**
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CONTACT PERSON: **Elaine Duncan**
DATE PREPARED: **October 12, 2011**
TRADE NAME: **Dyna-EXTOR® II External Fixation System**
COMMON NAME: **External Fixation System**
CLASSIFICATION NAME: **bone fixation fastener**
PRO CODE: **KTT**

SUBSTANTIALLY EQUIVALENT TO:
This system is substantially equivalent to Howmedica Mono-tube system and components, Orthofix Penning system and Orthofix Minirail system and the Stryker-Howmedica Apex Pin according to materials used, configuration, indications for use, and as shown by comparative testing and testing to standards.

DESCRIPTION of the DEVICE:
The Dyna-EXTOR®II is unilateral external fixation device. The system has 4 detailed systems according to the intended use. The Dyna-EXTOR®II external fixation system is composed of pins or wires inserted into the bone, above and below the fracture or surgery site. These pins are then attached to a strong external frame. This allows the bone to be held relatively firmly, while some mobility and weight bearing can take place.

INDICATIONS FOR USE:

The Dyna-EXTOR(L) II and Dyna-EXTOR(M) II external fixation systems are intended for the treatment of bone conditions that can be corrected or improved by external skeletal traction or fixation, including osteotomy, arthrodesis, fracture and reconstructive surgery.

510(k) Summary-Continued

The Dyna-EXTOR(SM) II external fixation system is intended for use in upper extremity applications for the reduction, alignment and stabilization of intra-articular and extra-articular fractures, corrective osteotomies, and soft tissue deformities.

Dyna-EXTOR(ST) II external fixation system is intended for use in external fixation of fractures and/ or reconstruction of small bones, including metacarpal and metatarsal.

SUMMARY of TESTING:
Testing was conducted according to ASTM F1541-02.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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

Re: K110426
Trade/Device Name: Dyna-EXTOR II External Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: October 12, 2011
Received: October 14, 2011

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Erin L Keith

for 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): K110426 (pg 1/1)

Device Name: **Dyna-EXTOR II External Fixation System**

The Dyna-EXTOR(L) II and Dyna-EXTOR(M) II external fixation systems are intended for the treatment of bone conditions that can be corrected or improved by external skeletal traction or fixation, including osteotomy, arthrodesis, fracture and reconstructive surgery.

The Dyna-EXTOR(SM) II external fixation system is intended for use in upper extremity applications for the reduction, alignment and stabilization of intra-articular and extra-articular fractures, corrective osteotomies, and soft tissue deformities.

Dyna-EXTOR(ST) II external fixation system is intended for use in external fixation of fractures and/ or reconstruction of small bones, including metacarpal and metatarsal.

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

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

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