



March 15, 2018

BK MEDITECH Co., Ltd.
% Meredith L. May, MS, RAC
Vice President, Empirical Consulting
Empirical Testing Corporation
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K173180

Trade/Device Name: Mega Plus Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: February 23, 2018
Received: February 28, 2018

Dear Ms. May:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Ronald P. Jean -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Indications for Use	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement on last page.
510(k) Number (if known) K173180	
Device Name Mega Plus Spine System	
Indications for Use (Describe) The Mega Plus Spine System is intended 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: degenerative disc disease; spondylolisthesis; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).	
Type of Use (Select one or both, as applicable) ☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	
PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.	
FOR FDA USE ONLY	
Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)	

510(K) SUMMARY

Submitter's Name:	BK MEDITECH CO., LTD.
Submitter's Address:	58, Eunhaengnamu-ro, Yanggam-myeon, Hwaseong-si, Gyeonggi-do, 18633, KOREA, REPUBLIC OF
Submitter's Telephone:	82-31-352-9135
Contact Person:	Meredith L. May MS, RAC Empirical Consulting 719-337-7579
Date Summary was Prepared:	27 September 2017
Trade or Proprietary Name:	Mega Plus Spine System
Common or Usual Name:	Thoracolumbosacral Pedicle Screw System
Classification:	Class II per 21 CFR §888.3070 Device Classification
Product Code:	NKB
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Mega Plus Spine System is a top-loading multiple component, posterior spinal fixation systems which consist of pedicle screws (multi-axial, multi-axial long-arm, mono and long-arm), iliac screws, rods, locking bolts, cross-links and connectors. The Mega Plus Spine System will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion. The Mega Plus Spine System implant components are supplied non-sterile, single use and fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to the ASTM F136. Various sizes of these implants are available. Specialized instruments are also available for the application and removal of the Mega Plus Spine System.

INDICATIONS FOR USE

The Mega Plus Spine System is intended 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: degenerative disc disease; spondylolisthesis; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are identical between the subject and predicates:

- Indications for Use

- Principles of Operation
- Materials of Manufacture
- Implant Sizes

Table 5-1: Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K000236	International Synergy™ VLS	INTERPORE CROSS	Primary
K050979	S4 Spinal System	Aesculap®, Inc.	Additional
K111940	S 100 Pedicle Screw System	Renovis	Additional
K130176	Orthofix	Firebird Spinal Fixation System	Additional
K031175	Click'X	Synthes	Additional
K123549	Polaris Spinal System	Biomet	Additional
K113666	XIA 3 Spinal System	Stryker Spine	Additional

PERFORMANCE DATA

The Mega Plus Spine System has been tested in the following test modes:

- Static compression bending per ASTM F1717-15
- Static tension bending per ASTM F1717-15
- Static torsion per ASTM F1717-15
- Dynamic axial compression bending fatigue per ASTM F1717-15
- Component testing per ASTM F1798-13

The results of this non-clinical testing show that the strength of the Mega Plus Spine System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Mega Plus Spine System is substantially equivalent to the predicate device.