December 10, 2018

BK MEDITECH CO., LTD.
% Meredith L. May, MS, RAC
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K183080
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: December 4, 2018
Received: December 6, 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183080

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 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 Testing Corp. 719.337.7579
Date Summary was Prepared:	02 Nov 2018
Trade or Proprietary Name:	Mega Plus Spine System
Common or Usual Name:	Thoracolumbosacral Pedicle Screw System
Classification:	Class II per 21 CFR §888.3070
Product Code:	NKB
Classification Panel:	Division of Orthopedic Devices - Posterior Spine Device Branch

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Mega Plus Spine System is a top-loading multiple component, posterior spinal fixation system which consists 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 implant components are supplied non-sterile, single use and fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136 or cobalt chromium alloy (Co28-Cr6-Mo) that conform to ASTM F1537. Various sizes of these implants are available. Specialized instruments are also available for the application and removal of the Mega Plus Spine System. Modifications to the Mega Plus Spine System from the clearance in K173180 include the addition of CoCr rods, the addition of LED and deformity type rods, and the inclusion of non-anodized screws for all screw types and sizes.

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).

TECHNICAL 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
- Principle Operations
- Materials of manufacture
- Implant Sizes

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K173180	Mega Plus Spine System	BK MEDITECH CO., Inc.	Primary
K111940	S 100 Pedicle Screw System	Renovis	Additional
K130176	Orthofix	Firebird Spinal Fixation System	Additional
K113666	XIA 3 Spinal System	Stryker Spine	Additional

PERFORMANCE TESTING SUMMARY

In support of this Special 510(k) Device Modification Premarket Notification, BK MEDITECH CO., LTD. has conducted confirmatory mechanical testing and provided an engineering rationale to demonstrate that the modifications to the Mega Plus Spine System provide adequate and substantially equivalent mechanical strength for their intended use.

CONCLUSION

The Mega Plus Spine System modified is very similar to previously cleared Mega Plus Spine System. The subject Mega Plus Spine System has similar intended uses, indications, technological characteristics, and principles of operation as the predicate devices. The modifications raise no new types of safety or effectiveness questions. The overall technology characteristics and mechanical performance data lead to the conclusion that the Mega Plus Spine System is substantially equivalent to the predicate devices.