



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

New Era Orthopaedics, LLC  
% Mr. Kenneth C. Maxwell II  
Empirical Testing Corporation  
4628 Northpark Drive  
Colorado Springs, Colorado 80918

April 8, 2015

Re: K150647  
Trade/Device Name: Polyscrew Pedicle Screw System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class II  
Product Code: MNI, MNH  
Dated: March 5, 2015  
Received: March 12, 2015

Dear Mr. Maxwell:

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 contact the Division of Industry and Consumer Education 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>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

**Mark N. Melkerson -S**

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

Enclosure

**Indications for Use**

510(k) Number (if known)  
**K150647**

Device Name  
**Polyscrew Pedicle Screw System**

Indications for Use (Describe)

The New Era Orthopaedics Polyscrew Pedicle Screw 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 thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), spinal tumor, pseudarthrosis and failed previous fusion.

The New Era Orthopaedics Polyscrew Pedicle Screw System is also intended for non-cervical pedicle screw fixation for the following indications: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. It is also intended for the following indications: trauma (i.e. fracture or dislocation); spinal stenosis; deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor; pseudoarthrosis; and failed previous fusion.

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)

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

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## 5. 510(K) SUMMARY

Submitter's Name:	Mark De Baca New Era Orthopaedics
Submitter's Address:	1214 Research Boulevard - Suite 1019 Hummelstown, PA
Submitter's Telephone:	717.585.6785
Contact Person:	Kenneth C. Maxwell Empirical Testing Corp. 719.291.6874
Date Summary was Prepared:	07 April 2015
Trade or Proprietary Name:	Polyscrew Pedicle Screw System
Common or Usual Name:	Pedicle Screw System
Classification:	Class II per 21 CFR §888.3070
Classification Name:	Pedicle screw spinal system
Product Code:	MNI, MNH
Classification Panel:	Division of Orthopedic Devices

### DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The New Era Orthopaedics™ (NEO) Polyscrew Pedicle Screw System is designed to provide mechanical support while biologic fusion takes place. It has been developed with the objective of providing the surgeon with an adaptable fixation system in order to carry out dorsal stabilization of the spine simply, quickly and effectively.

The New Era Orthopaedics™ (NEO) Polyscrew Pedicle Screw System is designed to provide mechanical support while biologic fusion takes place. Pedicle Screw System is a top loading, multiple component, posterior spinal fixation system which consists of pedicle screws, rods and cross links. All of the components are available in a variety of sizes to more closely match the patient's anatomy.

### CHANGE FROM PREVIOUSLY CLEARED SYSTEM

The purpose of this submission is to update the Surgical Technique to include in-situ assembly of the New Era Orthopaedics™ Polyscrew Pedicle Screw System cleared in K141253.

### INDICATIONS FOR USE

The New Era Orthopaedics Polyscrew Pedicle Screw 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 thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), spinal tumor, pseudarthrosis and failed previous fusion.

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#### TECHNICAL CHARACTERISTICS

No changes in technical characteristics have been made to the previously cleared New Era Orthopaedics™ Polyscrew Pedicle Screw System (K141253).

Table 5-1 Predicate Devices

<b>510k Number</b>	<b>Trade or Proprietary or Model Name</b>	<b>Manufacturer</b>	<b>Type</b>
K141253	Polyscrew Pedicle Screw System	New Era Orthopaedics	Primary
K124058	CREO™ Stabilization System	Globus Medical Inc.	Additional

#### SUMMARY OF PERFORMANCE TESTING

Per the risk analysis, the safety and efficacy of the device was established in the previously cleared New Era Orthopaedics™ Polyscrew Pedicle Screw System (K141253) and additional performance testing is not necessary.

#### CONCLUSION

The subject device is identical to the previously cleared New Era Orthopaedics™ Polyscrew Pedicle Screw System. The subject Polyscrew Pedicle Screw System has similar or identical intended uses, indications, technological characteristics, and principles of operation as the predicate devices. The modified surgical technique has been previously cleared in the CREO™ Stabilization System (K124058) and raises no new types of safety or effectiveness questions. The overall technological characteristics leads to the conclusion that the Polyscrew Pedicle Screw System is substantially equivalent to the predicate devices.