October 12, 2017

Mikron Makina Sanayi Ticaret Co. Ltd.
Mr. Mesut Köse
International Marketing Manager
Agac Isleri Sanayi Sitesi 1372. Sokak No: 31-Ostim
Ankara 06378
Turkey

Re: K171497
Trade/Device Name: Mikron Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: July 13, 2017
Received: July 17, 2017

Dear Mr. Köse:

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 (DICE) 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 (DICE) 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,

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)*
K171497

Device Name

Mikron Spinal Fixation System

Indications for Use *(Describe)*

Mikron Spinal Fixation System is a pedicle screw system indicated for the treatment of 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 attachment of a solid fusion.

Mikron Spinal Fixation System is also 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 spondylolisthesis with objective evidence of neurological impairment, 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.

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Section 3

510(k) Summary

(as required by 21 CFR 807.92)

3.1 Owner/Submitter Information

Owner: Mikron Makina Sanayi Ticaret Co. Ltd.

Address: Agac Isleri Sanayi Sitesi 1372. Sokak No: 31-Ostim
Ankara / Turkey 06378

Phone: 90.312.395 1700

Fax: 90.312.395 8729

Contact Person: Mesut Köse (Phone: 90.532.441 8629)

Date Prepared: 11 October 2017

3.2 Device Information

Common Name: Orthosis, Spinal Pedicle Fixation

Trade Name: Mikron Spinal Fixation System

Classification name: Thoracolumbosacral Pedicle Screw System
(per 21 CFR 888.3070)

Device Panel: Orthopedic

Product codes: NKB

Proposed Class: II

3.3 Substantial Equivalence

The proposed device is substantially equivalent to the device with the same trade name, Mikron Spinal Fixation System, which was FDA-cleared via 510(k) K130073, and BK Meditech's "MEGA 5.5 System" (K123476) -referred to as "Additional Predicate". These devices have the same intended use, technological characteristics and basic design as the proposed device. The only changes to Mikron Spinal Fixation System are new sizes and shapes added to the product span (i.e., adding various sizes of screws, and different size and shapes (straight and pre-bent) of rods).

3.4 Device Description

The Proposed Device is a top-loading multiple component, posterior spinal fixation system consisting of polyaxial pedicle screws, rods (Straight and pre-bent) and setscrews. The Mikron Spinal Fixation System will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion. The Mikron Spinal Fixation System is supplied non-sterile, single use and fabricated from titanium alloy (Ti6Al4V-ELI) that conforms to ASTM F136.

3.5 Indications for Use

Mikron Spinal Fixation System is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogeneous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attachment of a solid fusion.

Mikron Spinal Fixation System is also 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 spondylolisthesis with objective

evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

3.6 Technical Comparison

The summary of the technological characteristics of The Proposed Device compared to the predicate devices is as follows:

3.6.1 Material

All subject devices are fabricated of the same material, which is titanium alloy (Ti6Al4V-ELI) that conforms to ASTM F136.

3.6.2 Design

The Proposed Device and Predicate Devices have similarly designed but different sized screws and different sized and shaped (Straight and Pre-bent) rods. They both have same top-loading interconnection mechanism with same setscrew. The design incorporates the same design features as the predicate over new lengths and diameters to create a complete range of sizes for the surgeon. The system is attached to the vertebral body by means of screws at the non-cervical spine.

3.6.3 Function

All subject devices have the same function, which is acting as a spinal implant construct to stabilize and promote spinal fusion.

3.6.4 Level of Attachment

Levels of fixation of the Proposed and the Predicate Devices are for the thoracic, lumbar and sacral spine.

3.6.5 Intended Use

The Proposed Device is indicated for the identical intended uses as the predicate devices:

All devices are indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogeneous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attachment of a solid fusion. Mikron Spinal Fixation System is also 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 spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

3.6.6 Sterility

All devices are supplied non-sterile and for single use.

3.7 Non-Clinical Performance Testing

Non-clinical testing including static compressive, static torsion and dynamic compressive tests according to ASTM F1717, torsion test and pullout test for screws according to ASTM F543, axial gripping capacity and torsional gripping capacity according to ASTM F1798 and static and dynamic 4-point bending according to ASTM F2193 were conducted. The results demonstrate that the Proposed Device is substantially equivalent to the legally marketed predicate devices.

A Risk Analysis was also prepared and showed that the proposed changes do not present any additional risks.