November 15, 2022

Taeyeon Medical Co., Ltd.
% Priscilla Chung
Official Correspondent
LK Consulting Group USA, Inc.
18881 Von Karman Ave. STE 160
Irvine, California 92612

Re: K212700
Trade/Device Name: Dyflex-II
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: September 23, 2022
Received: September 26, 2022

Dear Priscilla Chung:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin O'neill -S

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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 below.

510(k) Number *(if known)*
K212700

Device Name

Dyflex-II

Indications for Use *(Describe)*
The Dyflex-II is a pedicle screw system indicated for the treatment of severe Spondylolisthesis (Grade 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.

In addition, the Dyflex-II 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 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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510(k) Summary

(K212700)

This summary of 510(k) is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: Oct 20, 2022

1. 510K Applicant / Submitter:

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2. Submission Contact Person

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3. Device

- Proprietary Name: Dyflex-II
- Common Name: Pedicle Screw Spinal Fixation System
- Classification: Class II (21 CFR 888.3070)
- Product Code: NKB

4. Predicate Device

4S™ Spinal System (K063708) by TAEYEON Medical Co., Ltd.

5. Description:

The Dyflex-II is a non-cervical pedicle screw and rod system intended to facilitate the surgical correction of spinal deformities by providing temporary internal fixation and stabilization during bone graft healing and/or fusion mass development. The Dyflex-II of screws, rods, cross-link connectors, and bolts that can be implanted via percutaneous surgical approach. The components are available in a variety of diameters and lengths in order to accommodate patient anatomy and are fabricated from titanium alloy (ASTM F 136). The

implants will be provided non-sterile and the user need to sterilize them before use.

8. Indications for Use

The Dyflex-II is a pedicle screw system indicated for the treatment of severe Spondylolisthesis (Grade 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.

In addition, the Dyflex-II 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 Spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

9. Substantial Equivalence Discussion:

9.1. Comparison table of the general device characteristics between the proposed and predicate device

	Subject Device	Predicate Device
Trade Name	Dyflex-II	4S™ Spinal System
Manufacturer	TAEYEON Medical Co., Ltd.	TAEYEON Medical Co., Ltd.
510(k) Number	K212700	K063708
Product Code	NKB	MNI, KWQ, MNH
Indications for Use	The Dyflex-II is a pedicle screw system indicated for the treatment of severe Spondylolisthesis (Grade 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. In addition, the Dyflex-II 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 Spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation,	The 4S™ Spinal System is a pedicle screw system indicated for the treatment of severe Spondylolisthesis (Grade 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. In addition, the 4S™ Spinal 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 Spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal

	scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).	tumor and failed previous fusion (pseudarthrosis).
Materials	Titanium Alloy (ASTM F 136)	Titanium Alloy (ASTM F 136)
Components	Screw, Cross-link Connector, Rod, Bolt	Screw, Cross-link Connector, Rod, Bolt
Screw Size	Diameters : 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0,8.5, 9.0mm Lengths : 30 to 50mm	Diameters : 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0mm Lengths : 30 to 55mm
Rod Size	Diameter : 5.5, 6.0mm Lengths : 30 to 200mm	Diameters : 5.5, 6.0mm Lengths: 30 to 200mm
Mechanical Testing	Performed according to ASTM F 1717	Performed according to ASTM F 1717

*Note: Mechanical testing for the subject device and the predicate device was performed according to ASTM F 1717.

9.2. Substantial Equivalence Discussion

The Dyflex-II has the same indications for use, technological characteristics, material, and principles of operation as the predicate device. It is substantially equivalent to the predicate device in design and function. The size range of the predicate device covers the subject device range as well.

The exterior design of the subject device is slightly different from the predicate device but the test results of the performance tests support that the subject device is substantially equivalent to the predicate device.

10. Performance Tests (Non-clinical)

- Sterilization Validation Tests in accordance with ISO 17665-1 and ISO 17665-2
- Performance Tests in accordance with ASTM 1717 including the following test items.
  - Static Torsion Test
  - Static Compression Bending test
  - Dynamic Compressive Fatigue Test

The test results of non-clinical tests performed on the subject device supported that it is substantially equivalent to the predicate devices despite the differences.

11. Conclusions:

Based on the information provided in this premarket notification, TAEYEON MEDICAL Co., Ltd. concludes that the Dyflex-II is substantially equivalent to the predicate device as described herein in.