February 23, 2026

Box Spine, LLC
% Hannah Taggart
Engineer & Regulatory Specalist
Applied Technical Services (Empirical Technologies)
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K253169
Trade/Device Name: Duet™ Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: January 21, 2026
Received: January 21, 2026

Dear Hannah Taggart:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253169

Device Name
Duet™ Spinal Fixation System

Indications for Use *(Describe)*

The Duet spinal fixation construct is intended to provide immobilization and stabilization of a single spinal segment in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of lumbar and sacral spine from L1-S1: degenerative disk disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spinal stenosis; 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED

K253169 510(K) SUMMARY

Submitter's Name:	Box Spine, LLC
Submitter's Address:	9524 E. 81st Ste B1614 Tulsa OK, 74133
Submitter's Telephone:	574-274-0186
Contact Person:	Hannah Taggart, MS, RAC ATS Colorado Springs 719- 457-1152 htaggart@atslab.com
Date Summary was Prepared:	January 21, 2026
Trade or Proprietary Name:	Duet™ Spinal Fixation System
Device Classification Name:	Thoracolumbosacral Pedicle Screw System
Classification & Regulation #:	Class II per 21 CFR §888.3080
Product Code:	NKB
Classification Panel:	Orthopedic – Spinal (DHT6B)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Duet™ Spinal Fixation System is a spinal fixation device intended to immobilize and stabilize spinal segments as an adjunct to fusion in the lumbar and sacral regions of the spine. The Duet™ Spinal Fixation System is a dual screw system that eliminates the need for standard pedicle system rods. All components of the Duet™ Spinal Fixation System are manufactured from Ti-6Al-4V ELI.

The Duet™ Spinal Fixation System construct of three components: halo-screw, sphere screw, and set screw. Both screws are offered in various lengths to accommodate individual patient anatomy. The Duet™ Spinal Fixation System is intended to be used at 1-level of the spinal segment to provide supplemental fixation.

INDICATIONS FOR USE

The Duet™ spinal fixation construct is intended to provide immobilization and stabilization of a single spinal segment in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of lumbar and sacral spine from L1-S1: degenerative disk disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spinal stenosis; pseudoarthrosis; and failed previous fusion.

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
- Materials of manufacture
- Structural support mechanism

Predicate Devices

510k #	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K201427	Trivergent Spinal Fixation System	Benvenue Medical, Inc.	NKB	Primary
K171838	TiLock2 Spinal System	Genesys Spine	NKB, KWP	Reference

The subject system offers similar indications for use, materials of manufacture, surgical approach, and screw size offerings as predicate devices. The differences in device components were evaluated during mechanical bench testing.

PERFORMANCE DATA

The Duet™ Spinal Fixation System has been tested in the following test modes:

- Static and dynamic compression bending testing per ASTM F1717
- Static torsion testing per ASTM F1717

The results of this non-clinical testing show that the strength of the Duet™ Spinal Fixation 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 Duet™ Spinal Fixation System is substantially equivalent to the predicate device.