



June 27, 2025

Spine Wave, Inc.
Ronald Smith
Executive Vice President - Quality, Regulatory and Clinical Affairs
Three Enterprise Drive, Suite 210
Shelton, Connecticut 06484

Re: K243816
Trade/Device Name: Testa TP Pivoting Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: June 6, 2025
Received: June 6, 2025

Dear Mr. Ronald Smith:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 systems (QS) regulation (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,

Katherine D. Kavlock -
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for

Brent Showalter, Ph.D.

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

Indications for Use

Submission Number (if known)

K243816

Device Name

Testa TP Pivoting Spacer System

Indications for Use (Describe)

The Testa™ TP Pivoting Spacer System with TiCell® Nano Advanced Surface Technology is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The Testa™ TP Pivoting Spacer System is to be used with autograft bone and/or allogenic bone graft composed of cortical, cancellous, and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. The Testa™ TP Pivoting Spacer System is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral body fusion device.

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) #: K243816

510(k) Summary

Prepared on: 2025-06-23

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Spine Wave, Inc.
Applicant Address	Three Enterprise Drive Suite 210 Shelton CT 06484 United States
Applicant Contact Telephone	203-712-1846
Applicant Contact	Mr. Smith Ronald
Applicant Contact Email	rsmith@spinewave.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Testa TP Pivoting Spacer System
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral Fusion Device With Bone Graft, Lumbar
Regulation Number	888.3080
Product Code(s)	MAX

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K100743	Atlas Spine Pivoting System	MAX
K231275	Exceed Biplanar Expandable Interbody System	MAX

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The Testa™ TP Pivoting Spacer System consists of new interbody implants that are provided sterile and intended to be surgically implanted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar intervertebral body fusion. The system is provided in a range of sizes to accommodate the anatomical needs for a range of patients and is designed with a central graft window to accommodate graft material. The implant features TiCell® Nano Advanced Surface Technology, a proprietary etched surface with micro and nano-scale features, on the superior and inferior latticed surfaces. This is intended to help with resistance to migration and to facilitate fusion. The components of the implant are fabricated from Titanium-6 Aluminum-4 Vanadium ELI (Ti-6Al-4V ELI) conforming to ASTM F3001 and ASTM F136.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The Testa™ TP Pivoting Spacer System with TiCell® Nano Advanced Surface Technology is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The Testa™ TP Pivoting Spacer System is to be used with autograft bone and/or allogenic bone graft composed of cortical, cancellous, and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. The Testa™ TP Pivoting Spacer System is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral body fusion device.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The Testa™ TP Pivoting Spacer System is substantially equivalent to the predicates. The Testa™ TP Pivoting Spacer System has the same intended use as the predicates. Specifically, the devices are intended to be used for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. Therefore, the subject Testa™ TP Pivoting Spacer System is substantially equivalent to its predicates in intended use, and no new issues of safety and effectiveness are raised.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The Testa™ TP Pivoting Spacer System has technological characteristics equivalent to those of the predicate device, including design, and material composition.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Nonclinical testing was performed on the Testa™ TP Pivoting Spacer System to support substantial equivalence to the predicate device. The following testing was performed:

- Static and dynamic axial compression testing per ASTM F2077
- Static and dynamic compression shear testing per ASTM F2077
- Subsidence testing per ASTM F2267
- Particulate and wear analysis per ASTM F1877

Clinical testing is not applicable.

Evaluation of the subject device performance data as compared to other legally marketed devices has found that the Testa™ TP Pivoting Spacer System is substantially equivalent.