November 18, 2025

Double Medical Technology Inc.
Joy Zuo
Official Correspondent
No.18, Shanbianhong East Road, Haicang District
Xiamen, Fujian 361026
China

Re: K252729
Trade/Device Name: Universal Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ, PGM
Dated: August 28, 2025
Received: August 28, 2025

Dear Joy Zuo:

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,

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252729

Please provide the device trade name(s).

Universal Spinal System

Please provide your Indications for Use below.

The Universal Spinal System is intended for non-cervical posterior and anterolateral fixation of the spine to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

When used for posterior, non-cervical, pedicle screw fixation in pediatric patients, the Universal Spinal System is indicated as an adjunct to fusion to treat progressive spinal deformities (i.e. scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Universal Spinal System is intended to treat pediatric patients diagnosed with spondylolisthesis/ spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. This system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The HOBBIT Growth Connectors are indicated in patients under 10 years of age with potential for additional spinal growth who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early-onset spinal deformities associated with thoracic insufficiency, including early-onset scoliosis, as part of a growing rod construct.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

1. Submitter	
Name	Double Medical Technology Inc.
Address	No. 18, Shanbianhong East Road, Haicang District, Xiamen, 361026, P. R. China
Phone	+86 592 6885079
Contact person	Yan Zuo
Date prepared	August 29th, 2025
2. Proposed Device	
Trade/proprietary name	Universal Spinal System
Classification name	Thoracolumbosacral Pedicle Screw System
Regulation number	21 CFR 888.3070(primary), 21 CFR 888.3050, 21 CFR 888.3060
Product code	NKB (primary), KWP, KWQ, PGM
Regulatory class	II
Classification panel	Orthopedic
3. Predicate Device	
Legally marketed device(s) to which equivalence is claimed	**Primary predicate device:** K040072 Medtronic CD HORIZON Spinal System **Additional predicate devices:** K113174 Medtronic CD HORIZON® Spinal System K222473 Expedium Spine System K963655 CD HORIZON™ Anterior Spinal System
Reason for 510(k) submission	New device(Implant)

4. Device Description

Universal Spinal System includes the HOBBIT 4.75 Spine System, HOBBIT 5.5/6.0 Spine System, HOBBIT MIS Spine System, HOBBIT 5.5/6.0 HA coated spine system and Anterior Thoracic-lumbar Spine System. Universal Spinal System consists of a variety of structures and sizes of pedicle screws, nut, rods, connectors, hook, transconnectors.

Universal Spinal System is made from Ti-6Al-4V ELI following ASTM F136 or Ti-6Al-4V following ASTM F1472 or Co-Cr-Mo following ASTM F1537.

The implants are provided as sterile or non-sterile, while the instruments are provided as non-sterile.

The implants are intended for single-use only, while the instruments are reusable.

5. Indications for Use

The Universal Spinal System is intended for non-cervical posterior and anterolateral fixation of the spine to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

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6. Comparison of Technological Characteristics with the Predicate Device

The rationale for substantial equivalence is based on consideration of the following characteristics:

Regulatory Classification: Same as the predicate devices

Indications for Use: Substantially equivalent (SE) to the predicate devices

Materials: Substantially equivalent (SE) to the predicate devices

Design Features: Substantially equivalent (SE) to the predicate devices

7. Non-Clinical Performance Data

7.1 Biocompatibility testing

The biocompatibility evaluation for the Universal Spinal System was conducted in accordance with the FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

7.2 Mechanical testing

The following tests were performed (per ASTM-F1717-21 *Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model.*) for the complete system of thoracolumbar spine.

- Static compression test
- Dynamic compression test
- Static torsion test
- Dynamic torsion test
- Static tension test

The following tests were performed (per ASTM F2193-20 *Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System*. and ASTM F543-17 *Standard Specification and Test Methods for Metallic Medical Bone Screws*) for the screw.

- Torsional properties test
- Driving torque test
- Axial pullout strength test

The following tests were performed (per ASTM-F1798-13 *Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants.*) for the components of the thoracolumbar system.

- Static axial gripping capacity test
- Static axial torque test

8. Clinical Data

No clinical performance data was provided to demonstrate substantially equivalence.

9. Conclusion

The information provided within this premarket notification demonstrates that proposed device is determined to be substantially equivalent (SE) to the predicate device.