Double Medical Technology Inc.
Yan Zuo
International RA Supervisor
No.18, Shanbianhong East Road, Haicang District
Xiamen, Fujian 361026
China

November 22, 2023

Re: K233078
Trade/Device Name: Posterior Cervical Spine System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG, KWP
Dated: September 20, 2023
Received: September 25, 2023

Dear Yan 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.

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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2023.11.22 08:22:10 -05'00'

for

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233078

Device Name
Posterior Cervical Spine System

Indications for Use *(Describe)*
The Posterior Cervical Spine System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7), and the thoracic spine from T1-T2:
(1)Traumatic spinal fractures and/or traumatic dislocations.
(2)Instability or deformity.
(3)Failed previous fusions (e.g. pseudarthrosis).
(4)Tumors involving the cervical spine.
(5)Degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

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.

510(k) Summary

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	September 20th, 2023
Proposed Device	
Trade/proprietary name	Posterior Cervical Spine System
Common or usual name	Posterior Cervical Spine System
Classification name	Posterior Cervical Screw System
Regulation number	21 CFR 888.3075, 21 CFR 888.3050
Product codes	NKG, KWP
Regulatory class	II
Classification panel	Orthopedic
Predicate Device	
Legally marketed device(s) to which equivalence is claimed	**Primary predicate device:** K210449 Infinity™ OCT System **Additional predicate device:** K142838 Synapse Occipital-Cervical-Thoracic (OCT) System
Reason for 510(k) submission	New device

Device Description

The Posterior Cervical Spine System consists of pedicle screws, nut, rods, connectors, hook, transconnectors, laminar hooks, occipital plates and occipital screw.

The implants in Posterior Spine Cervical System is made from Ti-6Al-4V ELI following ASTM F136 or Ti-6Al-4V following ASTM F1472.

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.

Indications for Use

The Posterior Cervical Spine System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of

the craniocervical junction, the cervical spine (C1 to C7), and the thoracic spine from T1-T2:

(1) Traumatic spinal fractures and/or traumatic dislocations.

(2) Instability or deformity.

(3) Failed previous fusions (e.g. pseudarthrosis).

(4) Tumors involving the cervical spine.

(5) Degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

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

Non-Clinical Performance Data

Biocompatibility testing

The biocompatibility evaluation for the Posterior Cervical Spine 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".

Mechanical testing

The following tests were performed per ASTM F2706-08 *Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model*, ASTM F543-17 *Standard Specification and Test Methods for Metallic Medical Bone Screws*, and ASTM F1798-13 *Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants* on Posterior Cervical Spine System to demonstrate substantial equivalence with the predicate device.

- Static axial compression bending test
- Static axial tensile bending test
- Static torsion test results

- Dynamic axial compression bending test
- Dynamic torsion test
- Torsional properties test
- Driving torque test
- Axial pullout strength test
- Static axial gripping capacity test
- Static axial torque test

Clinical Data

No clinical performance data was provided to demonstrate substantial equivalence.

Conclusion

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