December 19, 2025

Medicrea International S.A.S. (Medtronic)
Gautier Liegeon
Senior Regulatory Affairs Specialist
5389 Route De Strasbourg - Vancia
Rillieux-La-Pape, 69140
France

Re: K253577
Trade/Device Name: IB3D™ PL Spinal System (A24000000 / IB3D Universal Implant Inserter)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: November 14, 2025
Received: November 17, 2025

Dear Gautier Liegeon:

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,

Brent Showalter -S

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

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)*
K253577

Device Name
IB3D™ PL Spinal System (A24000000 / IB3D Universal Implant Inserter)

Indications for Use *(Describe)*
IB3D™ PL Spinal System is indicated for use in lumbar spinal fusion procedures for patients diagnosed with Degenerative Disc Disease (DDD) at 1 or 2 contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. When used for these indications, the IB3D™ PL Spinal System is intended for use with supplemental fixation systems cleared for use in the lumbar spine.
Additionally, the IB3D™ PL Spinal System can be used to provide anterior column support in patients diagnosed with degenerative scoliosis as an adjunct to pedicle screw fixation.
All patients should be skeletally mature and have had at least 6 months of nonoperative treatment. The IB3D™ PL Spinal System is intended to be used with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate when the subject device is used as an adjunct to fusion. These implants may be implanted via an open or a minimally invasive posterior or transforaminal approach. When implanting via posterior approach (PLIF), a minimum of two implants is required per spinal level.

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
IB3D™ PL Spinal System

Date prepared: December 18, 2025

I. Submitter information		
Submitter	MEDICREA INTERNATIONAL S.A.S. (MEDTRONIC) 5389 Route de Strasbourg – Vancia Rillieux-la-Pape, 69140 France Phone : 00 33 4 72 01 87 87	
Contact Person	Gautier Liegeon Regulatory Affairs Specialist MEDICREA INTERNATIONAL S.A.S. (MEDTRONIC)	
II. Device identification		
Trade name	IB3D™ PL Spinal System (A24000000 / IB3D Universal Implant Inserter)	
Classification Regulation	**Common Name**	Intervertebral Fusion Device With Bone Graft, Lumbar
	Product Code	MAX
	Regulation Number	21 CFR 888.3080
	Regulation Name	Intervertebral body fusion device
	Class	II
III. Predicate devices		
Primary predicate device	**Device name**	IB3D™ PL Spinal System
	510(k) information	K241164, cleared on 09/06/2024
	Common Name	Intervertebral Fusion Device With Bone Graft, Lumbar
	Product Code	MAX
	Regulation Number	21 CFR 888.3080
	Regulation Name	Intervertebral body fusion device
	Class	II
IV. Subject device description		
The IB3D Universal Implant Inserter is IB3D™ PL Spinal System instrument made of stainless steel. The Reusable Instruments are designed for use in orthopedic procedures to facilitate the insertion and rotation of IB3D™ PL implants into the lumbar spine. These instruments enable placement of the interbody implant between two lumbar vertebral bodies by allowing the implant to be inserted and rotated into its final position. The inserter comprises a handle and a shaft that securely holds the implant, with rotation achieved via the handle. The implant device is constructed from titanium alloy. (002_Device_Description)		
V. Intended use and indications for use		
Indications for use	IB3D™ PL Spinal System is indicated for use in lumbar spinal fusion procedures for patients diagnosed with Degenerative Disc Disease (DDD) at 1 or 2 contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at	

	the involved levels. When used for these indications, the IB3D™ PL Spinal System is intended for use with supplemental fixation systems cleared for use in the lumbar spine. Additionally, the IB3D™ PL Spinal System can be used to provide anterior column support in patients diagnosed with degenerative scoliosis as an adjunct to pedicle screw fixation. All patients should be skeletally mature and have had at least 6 months of nonoperative treatment. The IB3D™ PL Spinal System is intended to be used with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate when the subject device isused as an adjunct to fusion. These implants may be implanted via an open or a minimally invasive posterior or transforaminal approach. When implanting via posterior approach (PLIF), a minimum of two implants is required per spinal level.
VI. Comparison of technological characteristics	
The subject devices have similar fundamental scientific technology, overall design, dimensions, operative principle intended use, indications and sterilization as the primary predicate device. The subject device and the primary predicate device differ in that the subject device includes an additional component in its design, which enhances durability and supports its intended purpose. Otherwise, the subject device is substantially equivalent to the additional predicates presented in terms of manufacturing mechanism and material.	
VII. Performance data	
Nonclinical tests	The subject device demonstrated equivalent mechanical performance to the cited predicate device under the same test conditions.
Clinical tests	No clinical testing was used in order to support this submission.
VIII. Conclusion	
The overall technology characteristics and mechanical performance data lead to the conclusion that the subject device is substantially equivalent to legally marketed predicate devices.	