Globus Medical Inc
Jennifer Antonacci
Group Manager, Regulatory Affairs
Valley Forge Business Center
2560 General Armistead Ave
Audubon, Pennsylvania 19403

January 25, 2024

Re: K233735
Trade/Device Name: ADIRA™ Lateral Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ, OVD, MAX
Dated: November 21, 2023
Received: November 22, 2023

Dear Jennifer Antonacci:

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: 2024.01.25 11:52:11 -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)*
K233735

Device Name
ADIRA™ Lateral Plate System

Indications for Use *(Describe)*

ADIRA™ Lateral Plate System

The ADIRA™ 2-Hole and 4-Hole Plates, when used with screws only, are intended for use in the treatment of thoracolumbar (T1-L5) spinal instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (DDD, defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or failed previous spinal surgery.

The ADIRA™ 1-Hole Plate is intended to stabilize allograft or autograft at one level (T1-L5), aiding in spinal fusion and to provide temporary stabilization and augment development of a spinal fusion. It may be used alone or with other anterior, lateral, anterolateral, or posterior spinal systems. The device is not intended for load bearing applications.

ADIRA™ Plate-Spacer Assemblies

ADIRA™ Plates may be assembled to a lateral lumbar interbody fusion device (HEDRON® L, TransContinental®, RISE®-L, Modulus® XLIF, CoRoent®, or Cohere® XLIF Spacers) to create a plate-spacer assembly. When assembled to HEDRON® L, TransContinental®, or RISE®-L Spacers, the plate-spacer assembly is indicated for use at one or more levels of the lumbosacral spine (L1-L5), as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. When ADIRA™ Plates are assembled to Modulus® XLIF, CoRoent®, or Cohere® XLIF Spacers, the plate-spacer assembly takes on the indications of the interbody device.

ADIRA™ Plate-Spacers are intended to be used with screws and/or anchors which accompany the implants. These devices are intended for use with supplemental fixation (e.g. facet screws or posterior fixation). In addition, the 2-Hole or 4-Hole Plate-Spacers are intended for stand-alone use in patients with DDD at one or two levels only when <20° lordotic implants are used with two or four screws, respectively.

ADIRA™ Plate-Spacers are to be filled with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary: ADIRA™ Lateral Plate System

**Company:** Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

**Primary Contact:** Jennifer Antonacci, Ph.D.
Group Manager, Regulatory Affairs

**Date Prepared:** January 24, 2024

**Device Name:** ADIRA™ Lateral Plate System

**Common Name:** Thoracolumbar Plate System

**Classification:** Per 21 CFR as follows:
§888.3060 Spinal Intervertebral Body Fixation Orthosis
§888.3080 Intervertebral Body Fusion Device
Product Code(s): KWQ, OVD
Regulatory Class II, Panel Code: 87

**Primary Predicate:** PLYMOUTH™ Thoracolumbar Plate (K120092)

**Additional Predicates:** PLYMOUTH™ Thoracolumbar Plate (K181846)
InterContinental™ Plate-Spacer (K103382, K203278)
4WEB Lateral Spine Truss System Plating (K203065)
ELSA™ Spacers (K161379, K203278)

**Reference Devices:** NuVasive Thoracolumbar Interbody Systems: CoRoent, Modulus XLIF, Cohere, and others (K203714)

**Purpose:**
The purpose of this submission is to request clearance for the ADIRA™ Lateral Plate System.

**Device Description:**
The ADIRA™ Lateral Plate System consists of 4-, 2- and 1-hole thoracolumbar plates of various sizes to accommodate varying patient anatomy and surgical needs. The ADIRA™ plates are used with bone screws to attach to the anterolateral or lateral portion of the vertebral body of the thoracolumbar spine. ADIRA™ plates may also be attached to certain lateral lumbar interbody fusion devices (HEDRON L™, TransContinental™, RISE-L™, Modulus® XLIF, Cohere® XLIF, or CoRoent®) with an alignment screw. The plate-spacer assembly is used with bone screws and/or lateral anchors.

**Indications for Use:**

ADIRA™ Lateral Plate System

The ADIRA™ 2-Hole and 4-Hole Plates, when used with screws only, are intended for use in the treatment of thoracolumbar (T1-L5) spinal instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (DDD, defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or failed previous spinal surgery.

The ADIRA™ 1-Hole Plate is intended to stabilize allograft or autograft at one level (T1-L5), aiding in spinal fusion and to provide temporary stabilization and augment development of a spinal fusion. It may be used alone or with other anterior, lateral, anterolateral, or posterior spinal systems. The device is not intended for load bearing applications.

ADIRA™ Plate-Spacer Assemblies

ADIRA™ Plates may be assembled to a lateral lumbar interbody fusion device (HEDRON® L, TransContinental®, RISE®-L, Modulus® XLIF, CoRoent®, or Cohere® XLIF Spacers) to create a plate-spacer assembly. When assembled to HEDRON® L, TransContinental®, or RISE®-L Spacers, the plate-spacer assembly is indicated for use at one or more levels of the lumbosacral spine (L1-L5), as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. When ADIRA™ Plates are assembled to Modulus® XLIF, CoRoent®, or Cohere® XLIF Spacers, the plate-spacer assembly takes on the indications of the interbody device.

ADIRA™ Plate-Spacers are intended to be used with screws and/or anchors which accompany the implants. These devices are intended for use with supplemental fixation (e.g. facet screws or posterior fixation). In addition, the 2-Hole or 4-Hole Plate-Spacers are intended for stand-alone use in patients with DDD at one or two levels only when <20° lordotic implants are used with two or four screws, respectively.

ADIRA™ Plate-Spacers are to be filled with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone.

**Performance Data:**

Mechanical testing (static and dynamic compression bending and static torsion) was conducted in accordance with ASTM F1717, the “Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s”, May 3, 2004, and the “Guidance for Industry and FDA Staff: Spinal Plating Systems - Performance Criteria for

Safety and Performance Based Pathway," December 11, 2020. Expulsion testing was also conducted. Performance data demonstrate substantial equivalence to the predicate devices. Simulations demonstrated that the subject devices are not a worst case compared to the predicate devices in terms of MR compatibility.

**Technological Characteristics:**
The ADIRA™ implants have similar technological characteristics as the predicate devices including overall design, intended use, material composition, function, and range of sizes.

**Basis of Substantial Equivalence:**
The ADIRA™ Lateral Plate System has been found to be substantially equivalent to the predicate devices with respect to technological characteristics, performance, design, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate devices.