



June 10, 2026

Tyber Medical, LLC  
Rajan Kaur  
Senior Regulatory Affairs Specialist  
83 South Commerce Way, Suite 310  
Bethlehem, Pennsylvania 18017

Re: K260810  
Trade/Device Name: Anteralign LS coverplate  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral Body Fusion Device  
Regulatory Class: Class II  
Product Code: OVD  
Dated: March 12, 2026  
Received: March 12, 2026

Dear Rajan Kaur:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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](mailto: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

# 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.

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Please provide the device trade name(s).

?

Anteralign LS coverplate

Please provide your Indications for Use below.

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When used with Anteralign™ LS Spinal System, the Anteralign™ LS coverplate and cage is only intended to be used according to the indications of Medtronic's Anteralign™ LS Spinal System.

## Anteralign™ LS Spinal System Indications for Use

The Anteralign™ LS Spinal System is intended to be used in spinal fusion procedures on skeletally mature patients with symptomatic Degenerative Disc Disease (DDD, defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, and/or spinal stenosis, at one or two contiguous levels from L2 to S1 whose condition requires the use of interbody fusion. These patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. These patients should have had six months of nonoperative treatment prior to treatment with this device. Additionally, the Anteralign™ LS Spinal System and optional Anteralign™ LS Coverplate can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The Anteralign™ LS interbody cage may be used as a stand-alone device or in conjunction with supplemental fixation. The Anteralign LS™ interbody fusion Device e may be inserted via minimally invasive or open anterior or oblique approach at one or two contiguous levels from L2 to S1. These approaches include anterior and oblique. When used as a stand-alone device, the Anteralign™ LS cage must be used with 3 screws with devices that have standard lordosis ( $\leq 16^\circ$ ). If the physician chooses to use less than 3 screws or none of the provided screws, additional supplemental fixation in the lumbar spine must be used to augment stability. When used in patients as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity conditions, additional supplemental fixation (e.g. posterior fixation) must be used. Additionally, cages with lordosis angles  $16^\circ$  or greater are intended to be used with supplemental fixation (e.g. facet screws or posterior fixation).

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

Prescription Use ([21 CFR 801 Subpart D](#))

Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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## Contact Details

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

Applicant Name	Tyber Medical LLC
Applicant Address	83 South Commerce Way, Suite 310 Bethlehem PA 18017 United States
Applicant Contact Telephone	856-558-0632
Applicant Contact	Mrs. Rajan Kaur
Applicant Contact Email	rkaur@exalta.com

## Device Name

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

Device Trade Name	Anteralign LS coverplate
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral Fusion Device With Bone Graft, Lumbar
Regulation Number	888.3080
Product Code(s)	MAX, OVD

## Legally Marketed Predicate Devices

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

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K214010	Anteralign™ Spinal System with Titan nanoLOCK™ Surface Technology	MAX
K222465	Tyber Medical Anatomical Plating System	HRS

## Device Description Summary

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

The Anteralign™ LS coverplate System consists of a coverplate with a locking screw and an integrated locking mechanism. All implant components are manufactured from titanium alloy conforming to ASTM F136. The Anteralign™ LS coverplate may only be used with Medtronic's Anteralign™ LS Spinal System. The coverplate is not a required element for use of Medtronic's Anteralign™ LS Spinal System.

## Intended Use/Indications for Use

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

When used with Anteralign™ LS Spinal System, the Anteralign™ LS coverplate and cage is only intended to be used according to the indications of Medtronic's Anteralign™ LS Spinal System.

## Anteralign™ LS Spinal System Indications for Use

The Anteralign™ LS Spinal System is intended to be used in spinal fusion procedures on skeletally mature patients with symptomatic Degenerative Disc Disease (DDD, defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, and/or spinal stenosis, at one or two contiguous levels from L2 to S1 whose condition requires the use of interbody fusion. These patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. These patients should have had six months of nonoperative treatment prior to treatment with this device. Additionally, the Anteralign™ LS Spinal System and optional Anteralign™ LS Coverplate can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The Anteralign™ LS interbody cage may be used as a stand-alone device or in conjunction with supplemental fixation. The Anteralign

LS™ interbody fusion Device e may be inserted via minimally invasive or open anterior or oblique approach at one or two contiguous levels from L2 to S1. These approaches include anterior and oblique. When used as a stand-alone device, the Anteralign™ LS cage must be used with 3 screws with devices that have standard lordosis ( $\leq 16^\circ$ ). If the physician chooses to use less than 3 screws or none of the provided screws, additional supplemental fixation in the lumbar spine must be used to augment stability. When used in patients as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity conditions, additional supplemental fixation (e.g. posterior fixation) must be used. Additionally, cages with lordosis angles  $16^\circ$  or greater are intended to be used with supplemental fixation (e.g. facet screws or posterior fixation).

## Indications for Use Comparison

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

The subject device has the same indications for use as the predicate device.

## Technological Comparison

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

A comparison of the subject device and the predicate device demonstrated that the Anteralign LS coverplate is substantially equivalent to the previously cleared Anteralign Spinal System (K214010) in regards to the technological characteristic.

## Non-Clinical and/or Clinical Tests Summary & Conclusions

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

The following Non-clinical Testing was performed:

- 1) Clinical Simulation Validation
- 2) MR Testing
- 3) Mechanical Testing

Mechanical performance was assessed against the predicate device against the following FDA Guidance and test standards:

- 1) "Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Intervertebral Body Fusion Device",
- 2) ASTM F2077 "Standard Test Methods for Intervertebral Body Fusion Devices",
- 3) ASTM F2267 "Standard Test Method for Measuring Load-Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression",
- 4) DRAFT ASTM Z8423Z Static Push-Out Test Method for Intervertebral Body Fusion

The conclusions drawn from the nonclinical and clinical tests demonstrate that the subject device is as safe and effective, and performs as well as the legally marketed predicate device.

No clinical testing was performed.

Nonclinical testing concluded that the Anteralign LS Coverplate System is substantially equivalent to the Anteralign LS system currently on market. The coverplate does not introduce a new worst case construct in any of the test conditions, as provided in MEMO-X02-05-02A and TR-202535-X02-05.