January 27, 2022

Paradigm Spine
% Jessica Jho
Director of Regulatory Affairs
Surgalign Spine Technologies
520 Lake Cook Rd Suite 315
Deerfield, Illinois 60015

Re: K213493
Trade/Device Name: Fortilink with TiPlus Technology
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: October 29, 2021
Received: November 1, 2021

Dear Jessica Jho:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, 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)*

K213493

Device Name

Fortilink with TiPlus Technology

Indications for Use *(Describe)*

The Fortilink-C with TiPlus Technology is intended for spinal fusion procedures at one or more levels (C2-T1) in skeletally mature patients with cervical disc disease (defined as discogenic back pain with degeneration of the disc and/or myelopathy with herniated disc and/or osteophyte formation on posterior endplates confirmed by patient history and radiographic studies), instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion at one or more levels of the cervical spine with accompanying radicular symptoms. Implants are to be packed with autogenous bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. This device is intended to be used with an FDA-cleared supplemental fixation system appropriate for use in the cervical spine. This device is intended to be used in patients who have had six weeks of non-operative treatment.

The Fortilink-TS with TiPlus Technology is indicated for transforaminal and posterior interbody fusion (IBF) of the spine in skeletally mature patients with degenerative disc disease (DDD) and up to Grade 1 spondylolisthesis of the lumbar spine at one level or two contiguous levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These IBF devices are used to facilitate interbody fusion in the lumbar spine from L2 to S1 using autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. The IBF devices are intended to be used with FDA cleared supplemental fixation designed for the implanted level. Patients should have at least six months of non-operative treatment prior to treatment with an interbody fusion device.

The Fortilink-TC with TiPlus Technology is indicated for transforaminal interbody fusion (IBF) of the spine in skeletally mature patients with degenerative disc disease (DDD) and up to Grade 1 spondylolisthesis of the lumbar spine at one level or two contiguous levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These IBF devices are used to facilitate interbody fusion in the lumbar spine from L2 to S1 using autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. The IBF devices are intended to be used with FDA cleared supplemental fixation designed for the implanted level. Patients should have at least six months of non-operative treatment prior to treatment with an interbody fusion device.

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.

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This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER:

Paradigm Spine GmbH
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Wurmlingen Baden-Wurttemberg, DE 78573

Contact Person: Jessica Jho
Director of Regulatory Affairs
Surgalign Spine Technologies
Contact Email: JJho@surgalign.com

Date Summary Prepared: January 3, 2022

II. DEVICE

Trade or Proprietary Name: Fortilink with TiPlus Technology
Common Name: Intervertebral Body Fusion Device

Regulation Number: 21 CFR §888.3080
Classification: Class II
Product Code: ODP Intervertebral Body Fusion Device with bone graft, cervical
MAX Intervertebral Body Fusion Device with bone graft, lumbar

III. LEGALLY MARKETED PREDICATE DEVICES

510(K)	Product Name	Clearance Date
Primary Predicate Device		
K190498	Fortilink IBF System with TETRAfuse 3D Technology	July 5, 2019
Additional Predicate Devices		
K172343	Fortilink IBF System with TETRAfuse 3D Technology	October 23, 2017
K163673	Fortilink-C With TETRAfuse 3D Technology	May 23, 2017
K112496	T-Plus/Pioneer Interbody Fusion, Vertebral Body Replacement System	September 28, 2011

Reference Device		
510(K)	**Product Name**	**Clearance Date**
K171495	Zyston Strut Open Titanium Spacer System	January 31, 2018

IV. DEVICE DESCRIPTION

Fortilink with TiPlus Technology are implantable interbody fusion devices intended for use in the cervical and the lumbar spine. The subject device inserters are device specific accessories to be utilized during the procedure to insert the TiPlus Interbody devices into the disc space.

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Table 1. Comparison for Substantial Equivalence

Attribute	Subject Devices	Predicate Device	Predicate Device	Reference Device	Comparison Discussion
	Fortilink with TiPlus Technology Inserters	**Fortilink IBF System with TETRAfuse 3D Technology K163673, K172343, and K190498**	**T-Plus/Pioneer Interbody Fusion, Vertebral Body Replacement System K112496**	**Zyston Strut Open Titanium Spacer System K171495**	
Indications for Use	The Fortilink-C with TiPlus Technology is intended for spinal fusion procedures at one or more levels (C2-T1) in skeletally mature patients with cervical disc disease (defined as discogenic back pain with degeneration of the disc and/or myelopathy with herniated disc and/or osteophyte formation on posterior endplates confirmed by patient history and radiographic studies), instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion at one or more levels of the cervical spine with accompanying radicular symptoms. Implants are to be packed with autogenous bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. This device is	Cervical Interbody Fusion: When Fortilink-C is used as cervical interbody fusion (IBF) implants, these devices are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one level or two contiguous levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These IBF devices are used to facilitate interbody fusion in the cervical spine and are placed via an anterior approach from C2-C3 to C7-T1 using autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The IBF devices are intended to be used with supplemental fixation	The Pioneer IBF/VBR System, when used as an IBF implant, is indicated for intervertebral body fusion of the spine in skeletally mature patients. Pioneer IBFs are designed for use with autogenous bone graft to facilitate fusion. One device may be used per intervertebral space. Pioneer IBFs are intended to be used with supplemental spinal fixation cleared for the implanted level, such as the Quantum, Streamline, Contact ALP or SlimFuse systems. The Cervical IBF device in intended for use at one level in the cervical spine, from C3 to T I, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is to be used in patients who have had six weeks of non-operative treatment	When used as a lumbar intervertebral body fusion device, the Zyston Strut Open Titanium Interbody Spacer System is intended for spinal fusion procedures to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft in skeletally mature patients with degenerative disc disease (“DDD”) at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal	The indications for use of the subject devices are equivalent to the predicate devices. No new indications for use are introduced as a result of this submission.

Attribute	Subject Devices	Predicate Device	Predicate Device	Reference Device	Comparison Discussion
	Fortilink with TiPlus Technology Inserters	**Fortilink IBF System with TETRAfuse 3D Technology K163673, K172343, and K190498**	**T-Plus/Pioneer Interbody Fusion, Vertebral Body Replacement System K112496**	**Zyston Strut Open Titanium Spacer System K171495**	
	intended to be used with an FDA-cleared supplemental fixation system appropriate for use in the cervical spine. This device is intended to be used in patients who have had six weeks of non-operative treatment. The Fortilink-TS with TiPlus Technology is indicated for transforaminal and posterior interbody fusion (IBF) of the spine in skeletally mature patients with degenerative disc disease (DDD) and up to Grade 1 spondylolisthesis of the lumbar spine at one level or two contiguous levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These IBF devices are used to facilitate interbody fusion in the lumbar spine from L2 to S1 using autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to	cleared for the implanted level. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an interbody fusion device. Lumbar Interbody Fusion: When Fortilink-TS and Fortilink-L are used as lumbar interbody fusion (IBF) implants, these devices are indicated for intervertebral body fusion of the spine in skeletally mature patients with degenerative disc disease (DDD) and up to Grade1 spondylolisthesis of the lumbar spine at one level or two contiguous levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These IBF devices are used to facilitate interbody fusion in the lumbar spine from L1-L2 to L5-S1 using autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to	Lumbar IB's are also intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to SI1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. ODD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Lumbar lBFs are to be used in patients who have had six months of non-operative treatment. The Pioneer IRFIVBR System, when used as a VBR implant, is intended for use in the thoracolumbar spine (TI -L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. Pioneer VBRs are also indicated for treating fractures of the thoracic	level(s), and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The Zyston Strut Open Titanium Interbody Spacer System is to be implanted via a posterior approach and is to be combined with supplemental fixation. The titanium fusion devices are not indicated for vertebral body replacement.	

Attribute	Subject Devices	Predicate Device	Predicate Device	Reference Device	Comparison Discussion
	Fortilink with TiPlus Technology Inserters	**Fortilink IBF System with TETRAfuse 3D Technology K163673, K172343, and K190498**	**T-Plus/Pioneer Interbody Fusion, Vertebral Body Replacement System K112496**	**Zyston Strut Open Titanium Spacer System K171495**	
	facilitate fusion. The IBF devices are intended to be used with FDA cleared supplemental fixation designed for the implanted level. Patients should have at least six months of non-operative treatment prior to treatment with an interbody fusion device. The Fortilink-TC with TiPlus Technology is indicated for transforaminal interbody fusion (IBF) of the spine in skeletally mature patients with degenerative disc disease (DDD) and up to Grade 1 spondylolisthesis of the lumbar spine at one level or two contiguous levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These IBF devices are used to facilitate interbody fusion in the lumbar spine from L2 to S1 using autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or	facilitate fusion. The IBF devices are intended to be used with supplemental fixation cleared for the implanted level. Patients should have at least six (6) months of nonoperative treatment prior to treatment with an interbody fusion device.	and lumbar spine. Pioneer VBRs are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column, even in the absence of fusion for a prolonged period of time. The system must be used with the Pioneer® Quantum Spinal Fixation System or supplemental internal fixation systems cleared for the conditions listed above (i.e., tumor or trauma of TI -L5). Additionally, the Pioneer Vertebral Spacer implant is intended to be used with bone graft.		

Attribute	Subject Devices	Predicate Device	Predicate Device	Reference Device	Comparison Discussion
	Fortilink with TiPlus Technology Inserters	**Fortilink IBF System with TETRAfuse 3D Technology K163673, K172343, and K190498**	**T-Plus/Pioneer Interbody Fusion, Vertebral Body Replacement System K112496**	**Zyston Strut Open Titanium Spacer System K171495**	
	corticocancellous bone graft to facilitate fusion. The IBF devices are intended to be used with FDA cleared supplemental fixation designed for the implanted level. Patients should have at least six months of non-operative treatment prior to treatment with an interbody fusion device.				
Regulations, Product Code & Class	21 CFR 888.3080 ODP, MAX Class II	21 CFR 888.3080 ODP, MAX Class II	21 CFR 888.3080 21 CFR 888.3060 ODP, MAX, MQP Class II	21 CFR 888.3080 MAX Class II	The subject and predicate devices both are regulated per the identical CFR section and FDA product codes. There are no new intended uses being utilized in the subject devices as compared to the predicate.
Instrument Type	Orthopedic Manual Surgical Instrument – interbody inserter	Orthopedic Manual Surgical Instrument – interbody inserter	Orthopedic Manual Surgical Instrument – interbody inserter	Orthopedic Manual Surgical Instrument – interbody inserter	The subject devices are identical to the predicates.
Biocompatibility Patient Contact Duration	Limited patient contact duration (≤24 hours)	Limited patient contact duration (≤24 hours)	Limited patient contact duration (≤24 hours)	Limited patient contact duration (≤24 hours)	The subject devices are identical to the predicates.
Surgical Approach	Anterior cervical Posterior lumbar	Anterior cervical Posterior lumbar	Anterior cervical Posterior lumbar	Posterior lumbar	The subject devices are identical to the predicates.
Footprint	Cervical PLIF/TLIF Straight TLIF Curved	Cervical PLIF/TLIF Straight	TLIF Curved	TLIF Curved	The subject devices are identical to the predicate and reference devices. Note: Only the applicable

Attribute	Subject Devices	Predicate Device	Predicate Device	Reference Device	Comparison Discussion
	Fortilink with TiPlus Technology Inserters	**Fortilink IBF System with TETRAfuse 3D Technology K163673, K172343, and K190498**	**T-Plus/Pioneer Interbody Fusion, Vertebral Body Replacement System K112496**	**Zyston Strut Open Titanium Spacer System K171495**	
					footprint has been identified in this table.
Sterility	Non-Sterile devices provided with validated steam sterilization parameters to assure a SAL 10^{-6}	Non-Sterile devices provided with validated steam sterilization parameters to assure a SAL 10^{-6}	Non-Sterile devices provided with validated steam sterilization parameters to assure a SAL 10^{-6}	Non-Sterile devices provided with validated steam sterilization parameters to assure a SAL 10^{-6}	The subject devices are identical to the predicates.
Reusable/Single Use	Instruments are reusable	Instruments are reusable	Instruments are reusable	Instruments are reusable	The subject devices are identical to the predicates.

V. INDICATIONS FOR USE

The Fortilink-C with TiPlus Technology is intended for spinal fusion procedures at one or more levels (C2-T1) in skeletally mature patients with cervical disc disease (defined as discogenic back pain with degeneration of the disc and/or myelopathy with herniated disc and/or osteophyte formation on posterior endplates confirmed by patient history and radiographic studies), instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion at one or more levels of the cervical spine with accompanying radicular symptoms. Implants are to be packed with autogenous bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. This device is intended to be used with an FDA-cleared supplemental fixation system appropriate for use in the cervical spine. This device is intended to be used in patients who have had six weeks of non-operative treatment.

The Fortilink-TS with TiPlus Technology is indicated for transforaminal and posterior interbody fusion (IBF) of the spine in skeletally mature patients with degenerative disc disease (DDD) and up to Grade 1 spondylolisthesis of the lumbar spine at one level or two contiguous levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These IBF devices are used to facilitate interbody fusion in the lumbar spine from L2 to S1 using autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. The IBF devices are intended to be used with FDA cleared supplemental fixation designed for the implanted level. Patients should have at least six months of non-operative treatment prior to treatment with an interbody fusion device.

The Fortilink-TC with TiPlus Technology is indicated for transforaminal interbody fusion (IBF) of the spine in skeletally mature patients with degenerative disc disease (DDD) and up to Grade 1 spondylolisthesis of the lumbar spine at one level or two contiguous levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These IBF devices are used to facilitate interbody fusion in the lumbar spine from L2 to S1 using autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. The IBF devices are intended to be used with FDA cleared supplemental fixation designed for the implanted level. Patients should have at least six months of non-operative treatment prior to treatment with an interbody fusion device.

VI. TECHNICAL COMPARISON TO PREDICATE

The technological design features of the subject devices, such as intended use, indications for use, design, function and technology, were compared to the predicates and it was demonstrated that they are substantially equivalent.

VII. PERFORMANCE DATA

Engineering analysis and bench top testing of the inserters demonstrated that the modified designs do not present different issues of safety and effectiveness than the predicates.

VIII. CONCLUSION

Based on the information provided in this 510(k) submission, it has been determined that the subject devices are substantially equivalent to the legally marketed devices in regards to indication for use, intended use, design, technology, and performance.