October 7, 2020

Paradigm Spine, GmbH
% Mr. Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K201453
Trade/Device Name: Fortilink Cages with TiPlus Technology
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, ODP, OVD, OVE
Dated: July 2, 2020
Received: July 2, 2020

Dear Mr. Eggleton:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201453

Device Name
Fortilink-A Ti

Indications for Use *(Describe)*
The Fortilink-A Ti is indicated for anterior 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. Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior FDA cleared supplemental fixation.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201453

Device Name
Fortilink-C Ti

Indications for Use *(Describe)*
The Fortilink-C Ti 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201453

Device Name
Fortilink-L Ti

Indications for Use *(Describe)*
The Fortilink-L Ti is indicated for lateral 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201453

Device Name
Fortilink-SA Ti

Indications for Use *(Describe)*
The Fortilink-SA Ti is indicated for stand-alone anterior lumbar interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The system is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and is implanted via an anterior approach. Implants must be used with three of the provided bone screws. This system is to be used in patients who have had six months of non-operative treatment.
The Fortilink-SA Ti with lordotic angles greater than or equal to 20 degrees requires the use of FDA cleared supplemental fixation in addition to the screws intrinsic to the interbody spacer.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201453

Device Name
Fortilink-SC Ti

Indications for Use *(Describe)*
The Fortilink-SC Ti is intended for stand-alone anterior cervical interbody fusion procedures at one or two 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. The system is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and is implanted via an anterior approach. Implants must be used with two of the provided bone screws. This system is to be used in patients who have had six weeks of non-operative treatment.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201453

Device Name
Fortilink-TC Ti

Indications for Use *(Describe)*
The Fortilink-TC Ti 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201453

Device Name
Fortilink-TS Ti

Indications for Use *(Describe)*
The Fortilink-TS Ti 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

K201453 510(k) Summary

Device Trade Name: Fortilink Cages with TiPlus Technology

Manufacturer:
Paradigm Spine GmbH
Eisenbahnstrasse 84
78573 Wurmlingen, Germany
Phone: +49 7461 9635990

Contact:
Alberto Jurado (Director Quality and Regulatory Affairs)
Paradigm Spine GmbH
Eisenbahnstrasse 84
78573 Wurmlingen, Germany

Prepared by:
Mr. Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, DC 20001
jeggleton@mcra.com

Date Prepared: June 1st, 2020

Classifications: 21 CFR §888.3080, Intervertebral body fusion device

Class: II

Product Codes: MAX, ODP, OVD, OVE

Indications for Use:

Fortilink-C Ti

The Fortilink-C Ti 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.

Fortilink-SC Ti

The Fortilink-SC Ti is intended for stand-alone anterior cervical interbody fusion procedures at one or two 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. The system is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and is implanted via an anterior approach. Implants must be used with two of the provided bone screws. This system is to be used in patients who have had six weeks of non-operative treatment.

Fortilink-TS Ti

The Fortilink-TS Ti 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.

Fortilink-TC Ti

The Fortilink-TC Ti 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.

Fortilink-L Ti

The Fortilink-L Ti is indicated for lateral 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.

Fortilink-A Ti

The Fortilink-A Ti is indicated for anterior 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. Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior FDA cleared supplemental fixation.

Fortilink-SA Ti

The Fortilink-SA Ti is indicated for stand-alone anterior lumbar interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The system is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and is implanted via an anterior approach. Implants must be used with three of the provided bone screws. This system is to be used in patients who have had six months of non-operative treatment.

The Fortilink-SA Ti with lordotic angles greater than or equal to 20 degrees requires the use of FDA cleared supplemental fixation in addition to the screws intrinsic to the interbody spacer.

Device Description:

The purpose of this Traditional 510(k) is to seek marketing clearance for the Fortilink Cages with TiPlus Technology. The Fortilink Cages with TiPlus Technology are used to restore intervertebral height and to facilitate intervertebral body fusion in the spine using various surgical approaches with autogenous bone graft and/or allogenic bone graft materials. The Fortilink Cages with TiPlus Technology are intended to be used from on various spinal sections, depending on the cage. These devices can used with and without supplemental fixation (see **Section 11**).

The Fortilink Cages with TiPlus Technology are made from Ti-6Al-4V ELI (ASTM F3001) by an additive manufacturing process. The design contains solid structures and porous structures. The hollow geometry of the implants allows the cage to be packed with autogenous and/or allogenic bone graft.

Primary Predicate Device:

The Fortilink Cages with TiPlus Technology are substantially equivalent to the EIT Cellular Titanium Cage series line in device indications, surgical approach, design, materials, and performance.

Table 2: Primary Predicate Devices

Manufacturer	Device Name	K-Number
EIT Emerging Implant Technologies GmbH	EIT Cellular Titanium® Cervical Cages, EIT Cellular Titanium® PLIF Cages, EIT Cellular Titanium® TLIF Cages, EIT Cellular Titanium® ALIF Cages	K172888

Additional Predicate Devices:

The Fortilink Cages with TiPlus Technology are additional substantially equivalent to the Fortilink® Interbody Fusion Device (IFB) with TETRAfuse® 3D Technology (RTI Surgical, Inc.) (K192718), Unison®-C Anterior Cervical Fixation System (RTI Surgical, Inc.) (K170830), EIT Cellular Titanium® Lumbar Cage LLIF (EIT Emerging Implant Technologies GmbH) (K181644), Centinel STALIF M FLX™ (Centinel Spine, Inc.) (K173347), HEDRON™ Cervical Spacers (Globus Medical Inc.), Ax™ Stand-Alone ALIF System (Innovasis, Inc.), and EVOL® Spinal Interbody System (Cutting Edge Spine, LLC) with respect to indications, design, and performance.

Technological Characteristics:

The designs of the subject devices the Fortilink Cages with TiPlus Technology is based upon the same technology used by the primary predicate, EIT, to create the FDA-cleared and CE-marked EIT Cellular Titanium® PLIF, ALIF, and TLIF cages. Both the subject device and primary predicate cages are comprised of Ti-6Al-4V ELI through a 3D printing process called Selective Laser Melting (SLM), converting titanium alloy powder into a uniform, diamond mesh. The cage also contains hollow areas for bone graft packing to further facilitate fusion. Both devices were engineered by BAAT Medical, who designed the subject Paradigm Spine devices with the identical microstructure incorporated into the Fortilink cage designs.

Performance Testing Summary:

The testing of the Fortilink Ti Cages includes:

- Mechanical testing per ASTM F2077 and ASTM F2267: Static compression, static compression-shear, static torsion, dynamic compression, dynamic compression-shear, dynamic torsion, expulsion, and subsidence
- Biocompatibility testing for chemical characterization, particulate contaminations and cytotoxicity per ISO 10993.
- MRI Safety Testing per ASTM F2503-13, ASTM F2052-15, ASTM F2213-17, ASTM F2182-19e2, and ASTM F2119-07 (2013)

Substantial Equivalence:

The subject devices were demonstrated to be substantially equivalent to predicates cited in the passage above with respect to indications, design, materials, function, manufacturing, and performance.

Conclusion:

The Fortilink Cages with TiPlus Technology are substantially equivalent to the cited predicate devices with respect to its indications for use, design, function, materials, and performance.