June 6, 2023

CoreLink, LLC
% Mr. Justin Eggleton
VP, Spine Regulatory Affairs
MCRA
803 7th Street NW, 3rd Floor
Washington, District of Columbia 20001

Re: K230329
Trade/Device Name: F3D Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, OVE, PLR, MQP, MAX, OVD
Dated: March 9, 2023
Received: March 10, 2023

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 -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)*
K230329

Device Name
F3D-C2 Cervical Stand-Alone System

Indications for Use *(Describe)*
The F3D-C2 Cervical Stand-Alone System is a Stand-Alone anterior cervical interbody fusion system indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one or two contiguous disc levels depending on the assembly. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. The F3D-C2 Cervical Stand-Alone System is used to facilitate intervertebral body fusion in the cervical spine and is placed via an anterior approach at one- or two-disc levels (C2-T1) depending on the assembly. The interior of the spacers can be packed with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft and/or demineralized allograft bone with bone marrow aspirate as an adjunct to fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment. The F3D-C2 Cervical Stand-Alone System is an interbody fusion device intended to be used with two titanium alloy screws and/or anchors which accompany the implants. When used with screws, the F3D-C2 Cervical Stand-Alone System is intended for use at one or two levels of the cervical spine (C2-T1) and requires no additional fixation. When used with one or more anchors, the F3D-C2 Cervical Stand-Alone System is intended for use at one level of the cervical spine (C2-T1) and requires additional supplemental fixation such as posterior cervical screw 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)

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Device Name

F3D Corpectomy System

Indications for Use *(Describe)*

The F3D Corpectomy devices are vertebral body replacement devices intended for use in the cervical (C2-T1) and thoracolumbar spine (T1-L5). When used in the cervical spine (C2-T1), F3D Corpectomy devices are intended for use in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor fracture or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. These spacers are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion. When used in the thoracolumbar spine (T1-L5), F3D Corpectomy devices are intended for use to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture).

These spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period. The interior of the spacers can be packed with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft and/or demineralized allograft bone with bone marrow aspirate as an adjunct to fusion. These devices are intended to be used with FDA-cleared supplemental spinal fixation systems that have been labeled for use in the cervical, thoracic, and/or lumbar spine (i.e., posterior screw and rod systems, anterior plate systems, and anterior screw and rod systems). When used at more than two levels, supplemental fixation should include posterior 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)

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510(k) Number *(if known)*

K230329

Device Name

F3D Cervical Stand-Alone Interbody Fusion System

Indications for Use *(Describe)*

The F3D Cervical Stand-Alone System is a stand-alone anterior cervical interbody fusion system indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one or two contiguous disc levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. The F3D Cervical Stand-Alone System is used to facilitate intervertebral body fusion in the cervical spine and is placed via an anterior approach at one- or two-disc levels (C2-T1) using autograft bone. Patients should have at least six (6) weeks of non-operative treatment prior to treatment.

The F3D Cervical Stand-Alone Interbody Fusion System is intended to be used with the bone screw fixation provided and requires no additional fixation.

Type of Use *(Select one or both, as applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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Device Name

F3D™ Lateral System

Indications for Use *(Describe)*

The F3D™ Lateral System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Foundation implants are to be used with autogenous bone graft and supplemental fixation. Patients should have at least six (6) months of non- operative treatment prior to treatment with an intervertebral cage.

Type of Use *(Select one or both, as applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number *(if known)*
K230329

Device Name
M3™ Stand-Alone Anterior Lumbar System

Indications for Use *(Describe)*
The CoreLink® M3™ Stand-Alone ALIF System is a standalone interbody fusion system indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The device may be used with supplemental fixation.

Hyperlordotic implants (≥20° lordosis) are intended for use with supplemental fixation (e.g. posterior fixation) that are cleared for use in the lumbar spine. The system is indicated to be used with autograft bone. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.

The implants are intended to be used with the bone screws and lock provided. The system is designed to be a 3-screw implant, and all three (3) screws must be used. The accompanying lock must be used anytime the device is used with any number of screws. If the physician chooses to use less than the recommended number, or none of the provided screws, then the additional supplemental fixation in the lumbar spine must be used to augment 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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*
K230329

Device Name
Foundation 3D Anterior Lumbar System

Indications for Use *(Describe)*

Foundation 3D cervical implants are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as disco genic pain with degeneration of the disc confirmed by patient history and radiographic studies. Foundation cervical implants are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at one disc level (C2-T1) using autograft bone. Foundation 3D Interbody implants are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Foundation 3D lumbar implants are indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Foundation implants are to be used with autogenous bone graft and supplemental fixation. Patients should have at least six (6) months of nonoperative treatment prior to treatment with an intervertebral cage.

Type of Use *(Select one or both, as applicable)*

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510(k) Number *(if known)*
K230329

Device Name

Foundation™ 3D Interbody

Indications for Use *(Describe)*

The Foundation™ 3D Interbody Cervical Cage is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Foundation™ Cervical implants are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at one disc level (C2-T1) using autograft bone. Foundation™ 3D Interbody implants are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

The Foundation™ 3D Interbody Lumbar Cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Foundation™ implants are to be used with autogenous bone graft and supplemental fixation. Patients should have at least six (6) months of non- operative treatment prior to treatment with an intervertebral cage.

Type of Use *(Select one or both, as applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) SUMMARY

Submitter's Name:	CoreLink, LLC
Submitter's Address:	2072 Fenton Logistics Park St. Louis, MO 63026
Submitter's Telephone:	888-349-7808
Manufacturer Contact:	Steven Mounts Corelink, LLC 888-349-7808 s.mounts@corelinksurgical.com
Submission Contact:	Justin Eggleton Vice President, Spine Regulatory Affairs MCRA, LLC jeggleton@mcra.com
Date Summary was Prepared:	May 30, 2023
Trade or Proprietary Name:	F3D Interbody System
Common or Usual Name:	• Intervertebral Fusion Device with Bone Graft, Cervical • Intervertebral Fusion Device with Integrated Fixation, Lumbar • Intervertebral Fusion Device with Integrated Fixation, Cervical • Intervertebral Fusion Device with Bone Graft, Lumbar • Spinal Vertebral Body Replacement Device • Spinal Vertebral Body Replacement Device - Cervical
Classification:	Class II devices per: 21 CFR §888.3080 and 21 CFR §888.3060
Product Codes:	• ODP • OVD • OVE • MAX • MQP • PLR
Classification Panel:	Orthopedic

DEVICE DESCRIPTION

The CoreLink, F3D Interbody System is a collection of additively manufactured, machined implants and associated instruments for surgical site preparation and implantation to provide mechanical support to the cervical and lumbar spine while arthrodesis occurs. The subject cages are additively manufactured from Ti-6Al-4V per ASTM F3001. Integration consists of additive Ti-6Al-4V (ASTM F3001) anchors (also referred to as nails) or machined Ti- 6A1-4V (ASTM F136 and ISO 5832-3) screws. The spacer and screw components are available in an assortment of dimensional combinations to accommodate the individual anatomic and clinical circumstances of each patient. The basic shape of the spacer is a trapezoidal column to provide surgical

stabilization of the spine. The inferior/superior aspects of the spacer incorporate a vertical cavity which can be packed with bone graft. The F3D Interbody System has open macroscopic 3D pores with a microscopic, roughened surface and nano scale features.

INDICATIONS FOR USE

F3D-C2 Cervical Stand-Alone System

The F3D-C2 Cervical Stand-Alone System is a Stand-Alone anterior cervical interbody fusion system indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one or two contiguous disc levels depending on the assembly. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. The F3D-C2 Cervical Stand-Alone System is used to facilitate intervertebral body fusion in the cervical spine and is placed via an anterior approach at one- or two-disc levels (C2-T1) depending on the assembly. The interior of the spacers can be packed with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft and/or demineralized allograft bone with bone marrow aspirate as an adjunct to fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment. The F3D-C2 Cervical Stand-Alone System is an interbody fusion device intended to be used with two titanium alloy screws and/or anchors which accompany the implants. When used with screws, the F3D-C2 Cervical Stand-Alone System is intended for use at one or two levels of the cervical spine (C2-T1) and requires no additional fixation. When used with one or more anchors, the F3D-C2 Cervical Stand-Alone System is intended for use at one level of the cervical spine (C2-T1) and requires additional supplemental fixation such as posterior cervical screw fixation..

F3D Corpectomy System

The F3D Corpectomy devices are vertebral body replacement devices intended for use in the cervical (C2-T1) and thoracolumbar spine (T1-L5). When used in the cervical spine (C2-T1), F3D Corpectomy devices are intended for use in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor fracture or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. These spacers are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion. When used in the thoracolumbar spine (T1-L5), F3D Corpectomy devices are intended for use to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture).

These spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period. The interior of the spacers can be packed with autograft or allogenic bone

graft comprising cancellous and/or corticocancellous bone graft and/or demineralized allograft bone with bone marrow aspirate as an adjunct to fusion. These devices are intended to be used with FDA-cleared supplemental spinal fixation systems that have been labeled for use in the cervical, thoracic, and/or lumbar spine (i.e., posterior screw and rod systems, anterior plate systems, and anterior screw and rod systems). When used at more than two levels, supplemental fixation should include posterior fixation.

F3D Cervical Stand-Alone Interbody Fusion System

The F3D Cervical Stand-Alone System is a stand-alone anterior cervical interbody fusion system indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one or two contiguous disc levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. The F3D Cervical Stand-Alone System is used to facilitate intervertebral body fusion in the cervical spine and is placed via an anterior approach at one- or two-disc levels (C2-T1) using autograft bone. Patients should have at least six (6) weeks of non-operative treatment prior to treatment.

The F3D Cervical Stand-Alone Interbody Fusion System is intended to be used with the bone screw fixation provided and requires no additional fixation.

F3D™ Lateral System

The F3D™ Lateral System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Foundation implants are to be used with autogenous bone graft and supplemental fixation. Patients should have at least six (6) months of non- operative treatment prior to treatment with an intervertebral cage.

M3™ Stand-Alone Anterior Lumbar System

The CoreLink® M3™ Stand-Alone ALIF System is a standalone interbody fusion system indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The device may be used with supplemental fixation.

Hyperlordotic implants (≥20° lordosis) are intended for use with supplemental fixation (e.g. posterior fixation) that are cleared for use in the lumbar spine. The system is indicated to be used with autograft bone. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.

The implants are intended to be used with the bone screws and lock provided. The system is designed to be a 3-screw implant, and all three (3) screws must be used. The accompanying lock must be used anytime the device is used with any number of screws. If the physician chooses to use less than the recommended number, or none of the provided screws, then the additional supplemental fixation in the lumbar spine must be used to augment fixation.

Foundation 3D Anterior Lumbar System

Foundation 3D cervical implants are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as disco genic pain with degeneration of the disc confirmed by patient history and radiographic studies. Foundation cervical implants are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at one disc level (C2-T1) using autograft bone. Foundation 3D Interbody implants are to be used with supplemental fixation.

Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage. Foundation 3D lumbar implants are indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Foundation implants are to be used with autogenous bone graft and supplemental fixation. Patients should have at least six (6) months of nonoperative treatment prior to treatment with an intervertebral cage.

Foundation™ 3D Interbody

The Foundation™ 3D Interbody Cervical Cage is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Foundation™ Cervical implants are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at one disc level (C2-T1) using autograft bone. Foundation™ 3D Interbody implants are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

The Foundation™ 3D Interbody Lumbar Cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Foundation™ implants are to be used with autogenous bone graft and supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are identical between the subject and predicate devices:

- Indications for Use
- Materials of manufacture
- Sizes
- Biocompatibility
- Mechanical Performance

PREDICATE DEVICE(S)

Table 1: Predicate Device(s)

510k Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K200087	F3D Cervical Stand-Alone Interbody Fixation System	CoreLink, LLC	Primary
K211417	F3D-C2 Cervical Stand-Alone System	CoreLink, LLC	Additional
K202637	F3D Corpectomy System	CoreLink, LLC	Additional
K180814	CoreLink® M3™ Stand-Alone Anterior Lumbar System	CoreLink, LLC	Additional
K183239	CoreLink F3D™ Lateral System	CoreLink, LLC	Additional
K180556	Corelink Foundation 3D Anterior Lumbar System	CoreLink, LLC	Additional
K162496	Foundation™ 3D Interbody	CoreLink, LLC	Additional

PERFORMANCE DATA

Testing was performed for two purposes. First, to characterize the nano-scale features. Second, to evaluate and measure osteoblast functions on CoreLink F3D titanium alloy interbody devices and to determine a mechanism by which they influence such cell responses; completed testing included:

- Scanning Electron Microscopy
- Atomic Force Microscopy
- Energy Dispersive Spectroscopy
- Osteoblast Adhesion and Proliferation
- Total Intracellular Collagen Content
- Alkaline Phosphatase Activity
- Quantification of Extracellular Calcium

The results of the study showed that additively manufacturing Corelink's 3D printed Ti6Al4V created nanoscale surface features without changing chemistry with higher surface energy values compared to machined titanium alloy, PEEK, and HA-PEEK. This specific additive manufacturing process demonstrated that the 3D-Ti promoted higher osteoblast functions of adhesion, proliferation, and synthesis of a calcified extracellular matrix (as indicated by collagen, alkaline phosphatase, and calcium deposition) as compared to the machined titanium alloy, PEEK, and HA-PEEK.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the F3D Interbody System is substantially equivalent to the predicate device.