



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Life Spine, Incorporated
Randy Lewis
General Manager
13951 South Quality Drive
Huntley, Illinois 60142

September 2, 2016

Re: K160066

Trade/Device Name: Pro-link[®] Stand-Alone Cervical Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: August 5, 2016
Received: August 8, 2016

Dear Mr. Lewis:

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. 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 Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K160066

Device Name

Pro-Link® Stand-Alone Cervical Spacer System

Indications for Use (Describe)

The Pro-Link® Stand-Alone Cervical Spacer System is intended to be used with the screws provided and requires no additional supplementary fixation.

The Pro-Link® Stand-Alone Cervical Spacer System is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one disc level (C2-T1). DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. It is to be used in patients who have had at least six weeks of non-operative treatment. This device is intended to be used with autogenous bone graft.

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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510(k) Summary
Pro-Link® Stand-Alone Cervical Spacer System

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510(k) Contact: Randy Lewis
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Telephone: 847-884-6117
Fax: 847-884-6118

Date Prepared: August 15th, 2016

Trade Name: Pro-Link® Stand-Alone Cervical Spacer System

Common Name: Intervertebral Body Fusion Device

Classification: OVE, 21 CFR 888.3080, Class II

Primary Predicate : Pro-Link Cervical Spacer System (K121151)

Additional Predicate: Endoskeleton® TCS Interbody Fusion Device (K151596)

Device Description:

The Pro-Link® Stand-Alone Cervical Spacer System is intended to serve as an intervertebral body fusion device. The implant is available in a range of sizes and footprints to suit the individual pathology and anatomical conditions of the patient. It is fabricated and manufactured from either Titanium (Ti 6Al-4V ELI) or Polyetheretherketone (PEEK-OPTIMA LT1) with tantalum markers and titanium pins (Ti 6Al-4V ELI). The implant is hollow to permit packing with autogenous bone graft to help promote intervertebral body fusion. The superior and inferior surfaces have teeth to assist in the interface with the vertebral endplates to prevent rotation and/or migration. The implant has two pockets to permit placement of titanium bone screws (Ti 6Al-4V ELI) through the interbody to provide internal fixation. The implant also has one central threaded hole to permit the insertion of a titanium lock plate (Ti 6Al-4V ELI) to prevent screw back out.

Cmiko r ncpw'ctg'kpvpgf gf 'hqt'ukpi ng'wug'qpn' { 'cpf 'uj qwf 'pqv'dg'tgwugf 'wpf gt'cp{ "
ektewo ucpegu'Do not use any of the Pro-Link® Stand-Alone Cervical Spacer System
components with components from any other system or manufacturer. The Pro-Link®
Stand-Alone Cervical Spacer System components should never be reused under any
circumstances.

Intended Use of the Device<

Vj g'Rtq/Nkpn' 'Ucpcf/Cmpg'Egtxkcn'Ur cegt'U{ uvgö 'ku'kpvpgf gf 'vq'dg'wugf 'y kj 'yj g'uetgy u"
r tqxf gf "cpf 'tgs wktgu'pq'cf f kkpncn'ur r ngo gpvt { 'hz'cvkqp0'
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Vj g'Rtq/Nkpn' 'Ucpcf/Cmpg'Egtxkcn'Ur cegt'U{ uvgö 'ku'kpvpgf gf 'hqt'ur kpcn'hwkqp'r tqegf wtgu"
kp'ungrgvcn' 'o cwtg'r cvkpvu'y kj 'f gi gpgtcvkg'f kue'f kugcug'FFF +'cv'qpg'f kue'ngxgn'E4/V3-0"
FFF 'ku'f ghkpgf "cu'f kueqi gpk'r ckp'y kj 'f gi gpgtcvkg'qh'yj g'f kue'eqphko gf "d{ 'j kuvt { 'cpf "
tcf kqi ter j ke'uwf kgu'K'ku'vq'dg'wugf 'kp'r cvkpvu'y j q'j cxg'j cf 'cv'hcuv'ukz'y ggmi'qh'pqp/
qr gtcvkg'tgevo gpv0"Vj ku'f gxleg'ku'kpvpgf gf 'vq'dg'wugf 'y kj 'cwqi gpqwu'dqpg'i tch0'
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Technological Characteristics:

Vj g'Rtq/Nkpn' 'Ucpcf/Cmpg'Egtxkcn'Ur cegt'U{ uvgö 'ku'uwducpvcn' 'gs wxcrgpv'vq'yj g"
r tgf kecvg'u{ uvgö u'kp'vgtö u'qh'f guki p."ö cvgtkcn.'kpf kecvcqp'u'ht'wug'cpf 'uk'kpi 0'
"

Performance Data:

Hpkvg'grgo gpv'cpcn'uku."gpi kpggtkpi 'tcvkcpcg'cpf 'eqphko cvqt { "ö gej cplecn'vukpi 'eqpukvki "qh'ucvke"
eqo r tguukqp'cpf 'ucvke'vtukqp"eqpf wevgf 'kp'ceeqtf cpeg'y kj "öErcuu'KKU' gelcn'Eqvtqni'I wkf cpeg"
F qewo gpv'k'pvtxgtvgtcn'Hwukqp'F gxlegö.'Lwpg'34.'4229.'CUVO 'H4299.'y cu'r tguvgvf 'vq'f go qpvtcvg"
yj cv'pq'pgy 'y qtuv'ecug'eqpf kkp'y cu'kvtqf wevgf 'vq'yj g'Rtq/Nkpn' 'Ucpcf/Cmpg'Egtxkcn'Ur cegt"
U{ uvgö 0""
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Conclusion:

Vj g'Rtq/Nkpn' 'Ucpcf/Cmpg'Egtxkcn'Ur cegt'U{ uvgö 'y cu'uj qy p'vq'dg'uwducpvcn' 'gs wxcrgpv"
vq'yj g'r tgf kecvg'f gxlegu'kp'kpf kecvcqp'u'ht'wug.'f guki p.'hwpevkqp."ö cvgtkcn'wugf 'cpf "ö gej cplecn"
r gthqto cpeg0'