



Food and Drug Administration  
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SpineVision, S.A.  
Ms. Helene Plas  
Quality Assurance and Regulatory Affairs Manger  
10 rue de la Renaissance  
Bâtiment E  
92160 Antony  
FRANCE

April 4, 2016

Re: K160124  
Trade/Device Name: SpineVision LUMIS™ Cannulated Pedicle Screw Fixation System,  
SpineVision U.L.I.S.™ Pedicle Screw Fixation System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class II  
Product Code: MNI, MNH, KWQ, KWP  
Dated: February 19, 2016  
Received: March 7, 2016

Dear Ms. Plas:

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 yours,

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)

K160124

Device Name

SpineVision LUMIS™ Cannulated Pedicle Screw Fixation System  
SpineVision U.L.I.S.™ Pedicle Screw Fixation System

Indications for Use (Describe)

When used for anterior screw fixation or as a posterior, non-pedicle system of the non-cervical spine, the U.L.I.S.™ and LUMIS™ systems are indicated for:

- Degenerative disc disease (discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Fracture
- Spinal stenosis
- Tumors
- Failed previous fusion (pseudoarthrosis)

The U.L.I.S.™ and LUMIS™ systems are pedicle screw systems indicated for skeletally mature patients who:

- have severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebra;
- receive fusions using autogenous bone graft only;
- have the device fixed or attached to the lumbar and sacral spine (L3 to sacrum); and
- have the device removed after the development of a solid fusion.

In addition, the U.L.I.S.™ and LUMIS™ systems are pedicle screw systems intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine (T10-S1):

- Degenerative spondylolisthesis with objective evidence of neurologic impairment
- Fracture
- Spinal tumor
- Failed previous fusion (pseudoarthrosis)

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

Date	February 19, 2016
Submitter	SpineVision, S.A. 10 rue de la Renaissance Bâtiment E 92160 Antony France  Tel. +33(0)1 53 33 25 25 Fax +33(0)1 53 33 25 39
SpineVision Contact	Helene PLAS, QA&RA Manager  Tel: +33 1 53 33 25 25 Fax : + 33 1 53 33 25 39 corp.quality@spinevision.com
Trade Name	SpineVision LUMIS™ Cannulated Pedicle Screw Fixation System SpineVision U.L.I.S.™ Pedicle Screw Fixation System
Common Name Classification Name	Pedicle Screw Spinal System
Product code	MNI, MNH, KWQ, KWP
CFR section	888.3070, 888.3050
Legally marketed predicate devices	<u>Primary Predicate:</u> U.L.I.S.™ and LUMIS™ Pedicle Screw Fixation System (K133575)  <u>Additional predicates:</u> U.L.I.S.™ and LUMIS™ Pedicle Screw Fixation System (K130302/K112607) Xia Spinal System (K050461/K052761/K060361/K060748/K071373/K113666) VIPER® System, VIPER® 2 system (K061520/K111571/K090648/K102701) EXPEDIUM® Spine System (K041119/K062174/K090230/K090799)
<u>Description</u>	The SpineVision® Universal Lumbar Intuitive System (U.L.I.S.™ System), and Lumbar Universal Minimally Invasive System (LUMIS™ System) are composed of cannulated (LUMIS™) and non-cannulated (U.L.I.S.™) pedicle screws and fixation rods. Their components can be rigidly assembled in a variety of constructs, each corresponding to the needs and anatomy of a specific patient and are supplied non-sterile.

	<p>The purpose of this submission is to include new devices: the U.L.I.S.<sup>™</sup> Multi-Axial Reduction Screws, additional instruments to the U.L.I.S.<sup>™</sup> System; additional lengths for the LUMIS<sup>™</sup> Spinal Rods; and the use of LUMIS<sup>™</sup> Spinal Rods with U.L.I.S.<sup>™</sup> System.</p>
<p><u>Material</u></p>	<p>Titanium Ti-6Al-4V ELI complying with ASTM F136 (ISO 5832-3).</p>
<p><u>Intended use/ Indications for Use</u></p>	<p>When used for anterior screw fixation or as a posterior, non-pedicle system of the non-cervical spine, the U.L.I.S.<sup>™</sup> and LUMIS<sup>™</sup> systems are indicated for:</p> <ul style="list-style-type: none"> <li>• Degenerative disc disease (discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)</li> <li>• Spondylolisthesis</li> <li>• Fracture</li> <li>• Spinal stenosis</li> <li>• Tumors</li> <li>• Failed previous fusion (pseudoarthrosis)</li> </ul> <p>The U.L.I.S.<sup>™</sup> and LUMIS<sup>™</sup> systems are pedicle screw systems indicated for skeletally mature patients who:</p> <ul style="list-style-type: none"> <li>• have severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebra;</li> <li>• receive fusions using autogenous bone graft only;</li> <li>• have the device fixed or attached to the lumbar and sacral spine (L3 to sacrum); and</li> <li>• have the device removed after the development of a solid fusion.</li> </ul> <p>In addition, the U.L.I.S.<sup>™</sup> and LUMIS<sup>™</sup> systems are pedicle screw systems intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine (T10-S1):</p> <ul style="list-style-type: none"> <li>• Degenerative spondylolisthesis with objective evidence of neurologic impairment</li> <li>• Fracture</li> <li>• Spinal tumor</li> <li>• Failed previous fusion (pseudoarthrosis)</li> </ul>

<p>Summary of Technological Characteristics</p>	<p>The SpineVision Universal Lumbar Intuitive System (U.L.I.S.™ System), and Lumbar Universal Minimally Invasive System (LUMIS™ System) instrumentations are manufactured in Titanium Ti-6Al-4V ELI complying with ASTM F136. The devices provide correction and rigid stabilization of the spine during development of solid bone fusion following corrective spine surgery for a number of indications (listed above).</p>
<p>Performance data</p>	<p>The SpineVision® Universal Lumbar Intuitive System (U.L.I.S.™ System), and Lumbar Universal Minimally Invasive System (LUMIS™ System) conform to special control established for Pedicle Screw Spinal System and to “Spinal System 510(k)s – Guidance for Industry and FDA Staff Document” issued on May 3, 2004.</p> <p>No mechanical data is presented: no mechanical test is required for the added components. Performance evaluations were previously conducted on constructs representing the worst case components (static and dynamic axial compression and static torsion per ASTM F1717). Engineering analysis and design validation/verification were used to support substantial equivalence of the proposed components.</p> <p>No clinical data is presented.</p>
<p>Substantial equivalence</p>	<p>SpineVision Universal Lumbar Intuitive System (U.L.I.S.™ System), and Lumbar Universal Minimally Invasive System (LUMIS™ System) are substantially equivalent to their predicate devices in terms of intended use, material, design, mechanical properties and function.</p>
<p>Conclusion</p>	<p>SpineVision Universal Lumbar Intuitive System (U.L.I.S.™ System), and Lumbar Universal Minimally Invasive System (LUMIS™ System) are equivalent to the predicate devices.</p>