K082795

DEC 12 2008

SECTION 5 **510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

SUBMITTER INFORMATION

A.	Company Name:	Interventional Spine, Inc
B.	Company Address:	13700 Alton Parkway Suite 160 Irvine, CA 92618
C.	Company Phone:	(949) 472-0006
D.	Company Facsimile:	(949) 472-0016
E.	Contact Person:	Carol Emerson

DEVICE IDENTIFICATION

A.	Trade Name:	Single Use PERPOS™ PLS System, BONE-LOK® PLS Implant
B.	Catalog Number:	9045-01, 9045-02, LSW-45-3040
C.	Common Name:	Facet Screw and associated manual surgical instruments
D.	Classification Name:	Unclassified, various manual surgical instruments
E.	Product Code:	MRW
F.	Device Panel:	Orthopedic, General, and Plastic Surgery
G.	Device Class:	Unclassified

Predicate Devices

Triage Medical Disposable Posterior Lumbar Stabilization (PLS) Procedure Kit) K062391

Triage Medical BONE-LOK® 4.5mm Facet Screw and BONE-LOK® FS Instrument Kit K043351.

TranS1® Facet Screws K073515

DEVICE DESCRIPTION

The 4.5mm BONE-LOK® PLS Implant is a double-helix screw with a compression-locking collar made of medical grade titanium alloy and is provided "STERILE". The Single use PERPOS™ PLS System contains the 4.5mm BONE-LOK® PLS Implant

K082795

and disposable surgical instruments for use in implanting the device and is provided "STERILE". The re-usable Compression Tool is provided separately in a "NONSTERILE" condition; sterilization is by moist heat (steam autoclave) and is performed on-site.

INTENDED USE/INDICATIONS for USE

The 4.5mm BONE-LOK® PLS IMPLANT is indicated for spondylolisthesis, spondylolysis, degenerative disc disease (DDD) as defined by back pain of discogenic origin as confirmed by radiographic studies, degeneration of the facets with instability and fracture, pseudoarthrosis, or failed previous fusion.

The intended use of the 4.5mm BONE-LOK® PLS Implant is to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. The 4.5mm BONE-LOK® PLS Implant may be used to supplement legally marketed anterior fusion products in order to create an anterior/posterior fixation construction as an aid to fusion. The screws are inserted posteriorly through the superior side of the facet, across the facet joint and into the pedicle. The 4.5mm BONE-LOK® PLS Implant is intended for lumbar bilateral facet fixation, with or without bone graft, at single or multiple levels from L1 to S1. The intended use of the associated manual surgical instruments is to aid in the implantation of the 4.5mm BONE-LOK® PLS Implant.

TECHNOLOGICAL CHARACTERISTICS and SUBSTANTIAL EQUIVALENCE

Documentation was provided to demonstrate that the modified 4.5mm BONE-LOK® PLS Implant and PERPOS™ PLS System are identical or similar to the predicate devices in technological characteristics. The 4.5mm BONE-LOK® PLS Implant and PERPOS™ PLS System are substantially equivalent to the predicate devices in intended use, materials, design and technological characteristics.

page 2 of 2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Interventional Spine, Inc.
% Ms. Carol Emerson
13700 Alton Parkway, Suite 160
Irvine, California 92618

DEC 12 2008

Re: K082795
Trade/Device Name: Single Use PERPOS™ PLS System, 4.5 BONE-LOK® PLS Implant
Regulatory Class: Unclassified
Product Code: MRW
Dated: September 19, 2008
Received: September 25, 2008

Dear Ms. Emerson:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 **INDICATIONS FOR USE STATEMENT**

510(k) Number (if known): K082795

Device Name: Single Use PERPOS™ ™ PLS System, 4.5 BONE-LOK® PLS Implant

Indications For Use:
The 4.5mm BONE-LOK® PLS IMPLANT is indicated for spondylolisthesis, spondylolysis, degenerative disc disease (DDD) as defined by back pain of discogenic origin as confirmed by radiographic studies, degeneration of the facets with instability and fracture, pseudoarthrosis, or failed previous fusion.

The intended use of the 4.5mm BONE-LOK® PLS Implant is to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. The 4.5mm BONE-LOK® PLS Implant may be used to supplement legally marketed anterior fusion products in order to create an anterior/posterior fixation construction as an aid to fusion. The screws are inserted posteriorly through the superior side of the facet, across the facet joint and into the pedicle. The 4.5mm BONE-LOK® PLS Implant is intended for lumbar bilateral facet fixation, with or without bone graft, at single or multiple levels from L1 to S1. The intended use of the associated manual surgical instruments is to aid in the implantation of the 4.5mm BONE-LOK® PLS Implant.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K082795

page 1 of 1