



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

Interventional Spine, Incorporated  
Ms. Jane Metcalf  
Vice President, Quality Assurance, Regulatory and Clinical Affairs  
13700 Alton Parkway, Suite 160  
Irvine, California 92618

April 4, 2016

Re: K160464

Trade/Device Name: Opticage® Expandable Interbody Fusion Device  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: MAX  
Dated: March 17, 2016  
Received: March 18, 2016

Dear Ms. Metcalf:

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)  
K160464

K160464  
Page 1 of 1

Device Name  
Opticage® Expandable Interbody Fusion Device

### Indications for Use (Describe)

The Opticage® Expandable Interbody Fusion Device is a posterior lumbar intervertebral body fusion device and is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The Opticage Interbody Fusion Device can be implanted via posterior, transforaminal or lateral approach.

DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Candidates for surgery should be skeletally mature and have had six months of conservative treatment. These patients may have had primary or secondary surgery, but no previous fusion at the involved levels.

The device is not intended to be used as a stand-alone device. It must be used with supplemental internal spinal fixation systems that have been cleared for use in the lumbar spine (i.e. facet screw fixation systems, facet compression devices and posterior pedicle screw and rod systems).

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  
PRASStaff@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."*

# 510(k) Summary

K160464  
Page 1 of 2

**APPLICANT:** Interventional Spine, Inc.

**DATE PREPARED:** February 17, 2016

**CONTACT PERSON:** Jane Metcalf  
13700 Alton Parkway, Ste 160  
Irvine, CA 92618  
Phone: 949.525.1493  
Fax: 949.472.0016

**TRADE NAME:** Opticage® Expandable Interbody Fusion Device

**COMMON NAME:** Interbody Fusion Device

**CLASSIFICATION NAME:** Intervertebral Body Fusion Device

**DEVICE CLASSIFICATION:** Class II

**REGULATION NUMBER** 888.3080 (product code: MAX)

**PRIMARY PREDICATE  
DEVICE:** Opticage® Expandable Interbody Fusion Device (K152156)

## Purpose of Submission

The purpose of this special 510(k) submission is to obtain market clearance for twenty-four (24) additional models of the Opticage Expandable Interbody Fusion Device.

## Indication for Use and Intended Use

The Opticage® Expandable Interbody Fusion Device is a posterior lumbar intervertebral body fusion device and is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The Opticage Interbody Fusion Device can be implanted via posterior, transforaminal or lateral approach.

DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Candidates for surgery should be skeletally mature and have had six months of conservative treatment. These patients may have had primary or secondary surgery, but no previous fusion at the involved levels.

The device is not intended to be used as a stand-alone device. It must be used with supplemental internal spinal fixation systems that have been cleared for use in the lumbar spine (i.e. facet screw fixation systems, facet compression devices and posterior pedicle screw and rod systems).

## Device Description

The Opticage Expandable Interbody Fusion Devices are provided gamma sterilized and are for single use only. The devices are designed for lumbar intervertebral body fusion via posterior, transforaminal or lateral approach. They are fabricated from titanium alloy (Ti-6Al-4V) as per ASTM F136. Each device consists of five components: an upper and lower titanium plate, two titanium wedges and a central shaft. The faces of the upper and lower plates of the devices contain teeth and fenestrations to enhance bony in growth. The two titanium wedges are connected by the central shaft. The shaft can be rotated clockwise to move the wedges toward the center of the device thereby increasing the distance (i.e. height) between the upper and lower titanium plates. Alternatively, the shaft can be rotated counter clockwise to move the wedges away from the center of the device causing the distance (i.e. height) between the upper and lower plates to decrease. In this manner, the height of the construct can be continuously adjusted through a range of 5mm. A cavity internal to each device is intended to hold autogenous bone graft. The Opticage is available in a variety of configurations.

## Technical Characteristics

The modified devices contain an 8 degree lordotic angle. Otherwise, they have the same physical and technological characteristics as the predicate devices.

## Performance Tests

Design verification testing was conducted via Finite Element Analysis (FEA) to assess the device modification. The FEA results demonstrate that the performance of the device is substantially equivalent to that of the predicate.

## Basis for Determination of Substantial Equivalence

The predicate and the modified devices have identical intended uses. They are fabricated from the same material, are supplied in the same manner, have identical operating mechanisms and similar technological characteristics. Differences between the predicate and modified device do not raise any additional issues of safety or effectiveness