



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Incite Innovation  
% Ms. Renee Murphy  
Senior Regulatory Affairs Specialist  
Alphatec Spine, Incorporated  
5818 El Camino Real  
Carlsbad, California 92008

April 30, 2015

Re: K150913

Trade/Device Name: Incite Anchored Cervical Interbody Device  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: OVE  
Dated: April 3, 2015  
Received: April 6, 2015

Dear Ms. Murphy:

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 Part 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)  
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Device Name

Incite Anchored Cervical Interbody Device

Indications for Use (Describe)

The Incite Anchored Cervical Interbody Device 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 from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Incite Anchored Cervical Interbody Device is to be used with autogenous bone graft and implanted via an open, anterior approach. Supplemental fixation, i.e. an anterior cervical plate, is required to properly utilize this system.

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

### I. SUBMITTER

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John Kirwan, President  
Incite Innovation, LLC  
1500 Main Street, Suite 2410  
Springfield, MA 01115  
Phone: (413) 382-0210

Date Prepared: April 3, 2015

### II. DEVICE

*Name of Device:* Incite Anchored Cervical Interbody Device  
*Common or Usual Name:* Intervertebral Body Fusion Device  
*Classification Name:* Intervertebral Body Fusion Device  
*Regulatory Class:* II  
*Product Code:* OVE

### III. PREDICATE DEVICES

Incite Anchored Cervical Interbody Device, K130306, Primary Predicate  
Incite Anchored Cervical Interbody Device, K122008, Additional Predicate

### IV. DEVICE DESCRIPTION

The Incite Anchored Cervical Interbody (ACI) Device acts as a spacer to maintain proper Intervertebral and vertebral body spacing and angulation. The Incite Anchored Cervical Interbody Device is manufactured from PEEK and Ti 6Al 4V titanium alloy with tantalum radiopaque markers.

*Purpose of this 510(k) submission:* The purpose of this submission is to add the updated *ACI II Inserter* to the ACI System. The *ACI II Inserter* is used with the Incite Innovation Anchored Cervical Interbody Device. The inserter places the implant in the surgical site, deploys the anchor and detaches from the implant. The patient contacting material of the inserter is stainless steel (SS 17-4). The *ACI II Inserter* has been modified to be smaller, lighter in weight and easier to use.

### V. INDICATIONS FOR USE

The Incite Anchored Cervical Interbody Device 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 from C2-T1. DDD is defined as discogenic pain with

degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Incite Anchored Cervical Interbody

Device is to be used with autogenous bone graft and implanted via an open, anterior approach. Supplemental fixation, i.e. an anterior cervical plate, is required to properly utilize this system.

## **VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES**

The technological design features of the *ACI II Inserter* are similar to the previous version of the inserter. The design of the implant/device (ACI fusion device) has not changed since the predicate submission. Both versions of the ACI Inserter:

- Attach and detach from the Incite Innovation implant/anchor,
- Place the Incite Innovation implant into the surgical site and
- Deploy the anchor.

## **VII. PERFORMANCE DATA**

The following performance information is being provided in support of a substantial equivalence determination.

Design verification and validation was conducted for the *ACI II Inserter*. Design Verification included verification of the *ACI II Inserter* component dimensions performed through Device Interface Analysis (DIA). This analysis ensures that the interfacing components fit and function as specified for the components of the instrument as well as, the instrument with the implant. Design Validation was based on products requirements for the *ACI II Inserter* and on the previous inserter user validation methodology (*ACI Inserter, K122008 & K130306*). Design validation using a human cadaver demonstrated that the instrument met the user's needs in terms of overall use by attaching, placing, deploying and detaching from the implant.

Verification and validation data demonstrate that the performance and functionality of the *ACI II Inserter* is substantially equivalent to the ACI Inserter.

## **VIII. CONCLUSION**

Based upon the information provided in this Special 510(k) submission, it has been determined that the *ACI II Inserter* is substantially equivalent to the previous version of the inserter in regards to the Indications for Use, fundamental scientific technology, materials, labeling, packaging, and performance characteristics.

The subject and predicate ACI fusion device submissions, which include the two different ACI Inserter designs, were demonstrated to be substantially equivalent.