



## 510(k) SUMMARY

JAN 16 2014

## Zimmer® Dynesys® Top-Loading Spinal System

**Date of Summary Preparation:** *January 16, 2014*

**Submitter:** Zimmer Spine, Inc.  
7375 Bush Lake Road  
Minneapolis, MN 55439

**Manufacturer (Implants):** Zimmer GmbH  
Sulzerallee 8  
CH-8404 Winterthur  
Switzerland

**Establishment Registration Number:** 9613350 (Zimmer GmbH)

**Manufacturer (Instruments):** Zimmer Spine, Inc.  
7375 Bush Lake Road  
Minneapolis, MN 55439

**Establishment Registration Number:** 2184052 (Zimmer Spine)

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**Trade Name:** Dynesys® Top-Loading Spinal System

**Device Name (Common Name):** Spinal Fixation System

**Device Classification:** Class II

**Product Code(s):** NQP

**Regulation Number:** 21 CFR § 888.3070

**Regulation Description:** Posterior Metal/Polymer Spinal System, Fusion

**Predicate Devices:** Dynesys® Top-Loading Spinal System,  
K092234 cleared October 21, 2009

The purpose of this submission is to update the instrument labeling and to identify an alternative material vendor for a non-implanted component. This submission does not make any modifications to the subject dynamic stabilization device.

#### **General Device Description:**

The Zimmer® Dynesys® Spinal System, including the *Dynesys® Top-Loading Spinal System*, is a temporary implant system used to correct spinal deformity and facilitate the biological process of spinal fusion. This system is intended for non-cervical posterior use in the lumbar and sacral areas of the spine. Implants of this system consist of fixed pedicle screws of varying diameters and lengths, set screws, polycarbonate urethane (PCU) spacers and polyethylene terephthalate (PET) cords.

The *Dynesys®* pedicle screw consists of a top-loading solid or cannulated shank, either uncoated or coated with hydroxyapatite (HA). The *Dynesys®* Spinal System is also cleared for connection with the *Zimmer® DTO™* implant. The *Zimmer® DTO™* implant allows the connection of the *Dynesys®* Spinal System to the *OPTIMA™ ZS* Spinal System when the two systems are used on contiguous levels.

#### **Indications for Use:**

When used as a pedicle screw fixation system in skeletally mature patients, the *Dynesys* Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, and failed previous fusion (pseudoarthrosis).

In addition, when used as a pedicle screw fixation system, the *Dynesys* Spinal System is indicated for use in patients:

- Who are receiving fusions with autogenous graft only;
- Who are having the device fixed or attached to the lumbar or sacral spine;
- Who are having the device removed after the development of a solid fusion mass.

When the *Dynesys* Spinal System and the *OPTIMA ZS* Spinal System are used on contiguous levels, they must be used with the *Zimmer DTO* implant, rod-cord combination implant, and the U&I Corporation *OPTIMA ZS* Transition Screw. The indications for use for each level is as specified for each system.

#### **Summary of Technological Characteristics:**

The subject *Dynesys® Top-Loading Spinal System* generally shares the same technological characteristics as its cleared predicate device, *Dynesys® Top-Loading Spinal System*, as described in K092234. The characteristics include the same general design, same materials, same range of sizes, same performance characteristics and the same intended use.

The subject and predicate *Dynesys® Top-Loading Spinal System* both consist of screws, cords, spacers and the instruments necessary to implant the spinal system. The implant components and materials are listed in the table below. The implants are provided sterile by gamma irradiation. The orthopedic surgical instruments are manufactured from Stainless Steel that meets ASTM A564.

Device Description	Materials
Pedicle Screw	Protasul-100 (Titanium alloy (Ti-6Al-7Nb))
Set Screw	Protasul-100 (Titanium alloy (Ti-6Al-7Nb))
Pedicle Screw Coating	The top-loaded pedicle screw is offered in both coated and un-coated versions. The coating used is Hydroxyapatite (HA).
Cord	SULENE™-PET (polyethylene-terephthalate)
Plastic Spacers	Polycarbonate urethane (PCU)

The *Dynesys® Top-Loading Spinal System* is a temporary implant system used to correct spinal deformity and facilitate the biological process of spinal fusion. This system is cleared for non-cervical posterior use in the thoracic, lumbar and sacral areas of the spine. Implants of this system consist of fixed pedicle screws of varying diameters and lengths, set screws, polycarbonate urethane (PCU) spacers and polyethylene terephthalate (PET) cords. The subject *Dynesys® Top-Loading* pedicle screws consist of either a solid or cannulated shank, either uncoated or coated with hydroxyapatite (HA). The *Dynesys® Spinal System* was also cleared for connection with the *Zimmer DTO™* implant in K071879. The *Zimmer DTO™* implant allows the connection of the *Dynesys® Spinal System* to the *OPTIMA ZS Spinal System* when the two systems are used on contiguous levels.

#### Summary of Performance Testing:

The *Dynesys® Top-Loading Spinal System* is substantially equivalent to the predicate devices in design, materials, function and intended use.

Since this submission focuses on the instruments, no performance testing was performed on the implants. The subject *Dynesys® Top-Loading Spinal System* instruments were reviewed and tested appropriately for design validation, biocompatibility and sterilization. The test results conclude the subject *Dynesys® Top-Loading Spinal System* to be substantially equivalent to the predicate device, *Dynesys® Top-Loading Spinal System*.

- Cadaver lab testing of the subject *Dynesys® Top-Loading Spinal System* to evaluate human factors regarding the combination of instrument design changes as well as interaction with implants to confirm the substantial equivalence of the changes compared to the identified predicate device.
- Biocompatibility testing ensured the subject *Dynesys® Top-Loading Spinal System* materials are biocompatible after manufacturing based on the minor design changes made in comparison to the predicate devices.
- Sterilization, Dry Time and Cleaning testing ensured the subject *Dynesys® Top-Loading Spinal System* steam sterilization, cleaning and dry time instructions are substantially equivalent to the predicate devices for the instruments.

#### Substantial Equivalence:

Zimmer Spine considers the subject *Dynesys® Top-Loading Spinal System* product performance to be substantially equivalent to the predicate device, *Dynesys® Top-Loading Spinal System* (K092234), because there are no changes to the product performance specifications or device functional scientific technology.



January 16, 2014

Zimmer Spine, Incorporated  
Ms. Michelle Lenz  
Regulatory Affairs Specialist  
7375 Bush Lake Road  
Minneapolis, Minnesota 55439

Re: K133164

Trade/Device Name: Dynesys® Top-Loading Spinal System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class II  
Product Code: NQP  
Dated: September 30, 2013  
Received: October 17, 2013

Dear Ms. Lenz:

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

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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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

**Lori A. Wiggins**

for  
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): K133164

Device Name: **Dynesys® Top-Loading Spinal System**

Indications for Use:

When used as a pedicle screw fixation system in skeletally mature patients, the *Dynesys Spinal System* is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, and failed previous fusion (pseudoarthrosis).

In addition, when used as a pedicle screw fixation system, the *Dynesys Spinal System* is indicated for use in patients:

- Who are receiving fusions with autogenous graft only;
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When the *Dynesys Spinal System* and the *OPTIMA ZS Spinal System* are used on contiguous levels, they must be used with the *Zimmer DTO* implant, rod-cord combination implant, and the U&I Corporation *OPTIMA ZS Transition Screw*. The indications for use for each level is as specified for each system.

Prescription Use  X  AND/OR Over-the Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

**Zane W. Wyatt -S**

(Division Sign-Off)

Division of Orthopedic Devices

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