



Food and Drug Administration
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SIGNUS Medizintechnik GmbH
% Mr. Kenneth C. Maxwell II
Regulatory and Quality Specialist
Empirical Testing Corporation
4628 Northpark Drive
Colorado Springs, Colorado 80918

April 14, 2016

Re: K151704
Trade/Device Name: DIPLOMAT® Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: April 13, 2016
Received: April 13, 2016

Dear Mr. Maxwell:

This letter corrects our substantially equivalent letter of April 13, 2016.

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" (21 CFR 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,

Caroline Rhim -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Indications for Use	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement on last page.
510(k) Number (if known) K151704	
Device Name DIPLOMAT® Spinal System	
Indications for Use (Describe) <p>The DIPLOMAT® Spinal System, when used as a posterior pedicle screw system, is 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:</p> <ul style="list-style-type: none"> - Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies) - Spondylolisthesis - Spinal stenosis - Fracture - Dislocation - Scoliosis - Kyphosis - Spinal tumor - Pseudoarthrosis - Failed previous fusion <p>In addition, the DIPLOMAT® Spinal System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.</p> <p>The DIPLOMAT® Spinal System is intended to be used with autograft and/or allograft.</p>	
Type of Use (Select one or both, as applicable) <input checked="" type="checkbox"/> Prescription Use (Part 21 CFR 801 Subpart D) <input type="checkbox"/> Over-The-Counter Use (21 CFR 801 Subpart C)	
PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.	
FOR FDA USE ONLY	
Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)	

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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“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.”

5. 510(K) SUMMARY

Submitter's Name:	SIGNUS Medizintechnik GmbH
Submitter's Address:	Industriestr. 2 63755 Alzenau / Germany
Submitter's Telephone:	+49 6023 9166-213
Contact Person:	Kenneth C. Maxwell Empirical Testing Corp. 719.291.6874
Date Summary was Prepared:	29 January 2016
Trade or Proprietary Name:	DIPLOMAT® Spinal System
Common or Usual Name:	Orthosis, Spinal Pedicle Fixation Orthosis, Spondylolisthesis Spinal Fixation Orthosis, Spinal Pedicle Fixation, For Degenerative Disc Disease Appliance, Fixation, Spinal Interlaminar
Classification:	Class III per 21 CFR §888.3070 Pedicle screw spinal system
Product Code:	NKB, MNI, MNH
Classification Panel:	87 Orthopedics Panel

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The DIPLOMAT® Spinal System is a multiple component posterior spinal fixation system which consists of pedicle screws, rods, and connectors. All of the components are available in a variety of sizes to match more closely to the patient's anatomy. All components are manufactured from Ti-6AL-4V ELI per ASTM F136 and cobalt chrome per ASTM F75. The safety and effectiveness of this device has not been established when used in conjunction with bone cement or for use with poor bone quality (e.g., osteoporosis, osteopenia). This device is intended only to be used with saline or radiopaque dye

INDICATIONS FOR USE

The DIPLOMAT® Spinal System, when used as a posterior pedicle screw system, is 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:

- Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Spinal stenosis
- Fracture
- Dislocation
- Scoliosis
- Kyphosis

- Spinal tumor
- Pseudoarthrosis
- Failed previous fusion

In addition, the DIPLOMAT® Spinal System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

The DIPLOMAT® Spinal System is intended to be used with autograft and/or allograft.

The indications for use for the Diplomat™ system is similar to that of the predicate device noted below in Table 5-1.

TECHNOLOGICAL CHARACTERISTICS

The SIGNUS Medizintechnik GmbH DIPLOMAT® is made from Ti-6AL-4V ELI per ASTM F136. The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Structural support mechanism
- Sterilization
- Principles of Operation

Table 5-1 Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Type
K000236	Synergy VLS Open	Interpore	Primary
K131820, K103490, K033901, K955348	Moss Miami Titanium	DePuy Spine Inc.	Additional
K081080	TSRH	Medtronic	Additional
K020279, K051971, K024096	OPTIMA™	U&I Corporation	Additional
K102870	Spine Proliant Screw System	Exactech	Additional
K120838	Matrix System	Synthes	Additional
K110280	Revlok	Globus	Additional
K123717	UCentum	Ulrich	Additional

PERFORMANCE DATA

The DIPLOMAT® has been tested in the following test modes:

- Static Compression-Bending Test per ASTM 1717-14
- Static Torsion Test per ASTM 1717-14
- Dynamic Compression-Bending Test per ASTM F1717-14

The results of this non-clinical testing show that the strength of the Diplomat is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the DIPLOMAT® Spinal System is substantially equivalent to the predicate device.