

**Section 5: 510(k) Summary**

**Company Name/Address:** Whiteside Biomechanics, Inc.  
12634 Olive Blvd.  
St. Louis, MO 63141  
P: 314-996-8540  
F: 314-996-8543

**Correspondent:** Debra Meyer

**Device Name:** Whiteside Biomechanics Spinal System

**Proprietary Name:** Whiteside Biomechanics Spinal System

**Common Name:** Spinal System

**Classification Name:** Spinal Intervertebral Body Fixation Orthosis  
Spinal Interlaminar Fixation Orthosis  
Spondylolisthesis Spinal Fixation Device  
System

**Substantial Equivalence To:** The Corin Spinal System  
(K973425)

**Device Description:**

A spinal system consisting of screws, hooks, washers, spacer and plates/screws. The pedicle screws are available in four diameters from 5mm to 8mm, and vary in length from 30mm to 55mm. The spinal rods have a diameter of 4.75mm and vary in length from 50mm to 500mm. The anterior washers offer use with 5mm, 6mm, and 7mm screws. The Conical spacers are available in three heights from 7mm to 12mm, increasing in 2.5 increments. The lumbo-sacral rod/plate and screw incorporates lumbo-sacral rod/plates in three lengths from 80mm to 120mm, and bone screws with a 7mm diameter and lengths of 30mm to 45mm, increasing in 5mm increments. There are five laminar hooks and one pedicle hook with the range.

**Device Intended Use:**

The system is intended for use anterolateral/anterior, non-pedicle posterior and posterior pedicle.

The distal tips of the pedicle screws are fluted to a point beyond the first thread, thus creating a self-tapping screw configuration.

The spinal rods have a diameter of 4.75mm and vary in length from 50mm to 500mm.

The locking mechanism between the rod and screw, as well as the rod and hook, features a three point clamping configuration in order to significantly reduce the risk of rod positioning and migration.

The devices are used to treat a number of spinal conditions.  
(See following)

**Device Indications for Use:**

- 1) The device system consisting of pedicle screws, washers, spacers, utilizing the anterolateral/anterior surgical approach is intended for the following uses:
  - a.) Anterolateral screw fixation to the non-cervical spine,
  - b.) Anterior screw fixation to the cervical spine.

The anterolateral/anterior system is intended for use in the following indications:

- a.) Degenerative disc disease of the lumbar, thoracic and cervical spine relating to discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies.
- b.) Spondylolisthesis
- c.) Trauma
- d.) Spinal Stenosis
- e.) Scoliosis
- f.) Kyphosis
- g.) Tumor
- h.) Pseudoarthrosis
- i.) Previous failed fusion

- 2.) The device system consisting of hooks, screws, washers, spacer, when utilized as a non-pedicle posterior system is intended for use in the following:

- a.) Hook and sacral/ilic screw fixation to the non-cervical spine.

The non-pedicle posterior system is intended for use in the following indications:

- a.) Degenerative disc disease of the lumbar, thoracic and cervical spine relating to discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies.
- b.) Spondylolisthesis
- c.) Trauma

- d.) Spinal Stenosis
  - e.) Scoliosis
  - f.) Kyphosis
  - g.) Tumor
  - h.) Pseudoarthrosis
  - i.) Previous failed fusion
- 3.) The device system of hooks, spacers, sacral/iliac screws and pedicle screws is intended for patients:
- a.) Having a severe spondylolisthesis (grades 3 and 4) at the L5-S1 joint:
  - b.) Who are receiving fusions using autogenous bone graft only:
  - c.) Who are having the device fixed or attached to the lumbar and sacral spine: and
  - d.) Who are having the device removed after the development of a solid fusion mass.

The devices are manufactured from Titanium Alloy ASTM F1472-93 or Stainless Steel ASTM F138. Only components manufactured from the same material may be used in combination.

**Technological Comparison:**

The Whiteside Biomechanics, Inc. Spinal System is a subset of the Corin USA Spinal System, the subset is identical to the predicate device. There are no different technological characteristics between the Whiteside Biomechanics Spinal System and the Corin Spinal System.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 12 1999

Ms. Debra Meyer  
Whiteside Biomechanics, Inc.  
12634 Olive Boulevard  
St. Louis, Missouri 63141

Re: K991678  
Trade Name: Whiteside Biomechanics Spinal System  
Regulatory Class: II  
Product Code: KWQ, KWP, and MNH  
Dated: May 13, 1999  
Received: May 17, 1999

Dear Ms. Meyer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (Premarket Approval), 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 895.

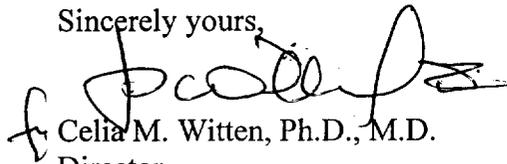
A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General Regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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.

Page 2 – Ms. Debra Meyer

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C. Witten', with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.

Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Section 11: Indications for Use**

**Device Indications for Use:**

- 1.) The device system consisting of pedicle screws, washers, spacers, utilizing the anterolateral/anterior surgical approach is intended for the following uses:
  - a.) Anterolateral screw fixation to the non-cervical spine,
  - b.) Anterior screw fixation to the cervical spine.

The anterolateral/anterior system is intended for use in the following indications:

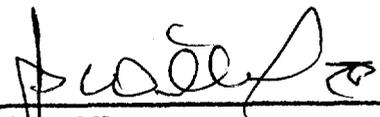
- a.) Degenerative disc disease of the lumbar, thoracic and cervical spine relating to discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies.
- b.) Spondylolisthesis
- c.) Trauma
- d.) Spinal Stenosis
- e.) Scoliosis
- f.) Kyphosis
- g.) Tumor
- h.) Pseudoarthrosis
- i.) Previous failed fusion

- 2.) The device system consisting of hooks, screws, washers, spacer, when utilized as a non-pedicle posterior system is intended for use in the following:

- a.) Hook and sacral/iliac screw fixation to the non-cervical spine.

The non-pedicle posterior system is intended for use in the following indications:

- a.) Degenerative disc disease of the lumbar, thoracic and cervical spine relating to discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies.
- b.) Spondylolisthesis
- c.) Trauma
- d.) Spinal Stenosis
- e.) Scoliosis
- f.) Kyphosis
- g.) Tumor
- h.) Pseudoarthrosis
- i.) Previous failed fusion

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K991678

Prescription Use X  
(Per 21 CFR 801.109)

- 3.) The device system of hooks, spacers, sacral/iliac screws and pedicle screws is intended for patients:
- a.) Having a severe spondylolisthesis (grades 3 and 4) at the L5-S1 joint:
  - b.) Who are receiving fusions using autogenous bone graft only:
  - c.) Who are having the device fixed or attached to the lumbar and sacral spine: and
  - d.) Who are having the device removed after the development of a solid fusion mass.

The levels of pedicle screws fixation are limited to L3-S1.

The devices are manufactured from Titanium Alloy: ASTM F138 or Stainless Steel: ASTM F1472-93. Only components manufactured from the same material may be used in combination.



(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K991678

Prescription Use X  
(Per 21 CFR 801.109)