

FEB 27 1998

510(k) SUMMARY

K973425

Name of Company:

Corin Spinal Systems Ltd.
The Corinium Centre
Cirencester
Gloucestershire
GL7 1YJ
England

Name of Device:

The Corin Spinal System

Device Description:

A spinal system consisting of screws, hooks, washers, spacers, rods, and rod 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 2.5mm 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 within the range.

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 pedicle screw lengths are offered in 5mm increments from 30mm to 55mm. The screw diameters are offered in 1mm increments from 5mm to 8mm diameters.

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 pistoning and migration.

The devices are used to treat a number of spinal conditions listed as follows:

INDICATIONS FOR USE

1. The device system consisting of 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) Revision of previous surgery
- (j) Neoplastia

2. The device system consisting of hooks, screws, washers, spacers, when utilized as a non-pedicle posterior system has the following intended use:

- (a) hook and sacral/iliac screw fixation to the non-cervical spine

The non-pedicle posterior devices may be used for 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) Revision of previous surgery
- (j) Neoplastia

3. The device system consisting 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
- (d) Who are having the device removed after the development of a solid fusion mass

The levels of pedicle screws fixation will be L3-S1.

The anterior washers can be used with either the 5mm, 6mm, or 7mm screws.

The Conical spacers are available in three heights, 7mm, 9.5mm, and 12mm.

The lumbo-sacral rod plate and screw incorporates lumbo-sacral rod plates with 80mm, 100mm, and 120mm rod lengths, as well as screws of a 7mm diameter and lengths that range from 30mm to 45mm, in 5mm increments.

The devices are manufactured from titanium alloy or stainless steel. All components are completely interchangeable with each other, but only components manufactured from the same material may be used in combination.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Craig Corrance
President
Corin USA
10500 University Center Drive
Suite 190
Tampa, Florida 33612

Re: K973425
Corin Spinal System
Regulatory Class: II
Product Codes: MNH, KWP and KWQ
Dated: December 16, 1997
Received: December 22, 1997

Dear Mr. Corrance:

We have reviewed your Section 510(k) notification of intent to market the device system referenced above and we have determined the device system is substantially equivalent (for the indications for use stated in the enclosure) to device systems marketed in interstate commerce prior to May 28, 1976 or to devices that have been reclassified in accordance with the provisions of the Federal, Food, Drug, and Cosmetic Act (Act). This decision is based on your device system being found equivalent only to similar device systems labeled and intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar - first sacral (L5-S1) vertebral 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. You may, therefore, market your device system subject to the general controls provisions of the Act and the limitations identified below.

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. Note that labeling or otherwise promoting this device system for pedicular screw fixation/attachment for indications other than severe spondylolisthesis, as described above, would cause the device system to be adulterated under 501(f)(1) of the Act.

This device system, when intended for pedicular screw fixation/attachment to the spine for indications other than severe spondylolisthesis, as described above, is a class III device under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing. Accordingly:

1. All labeling for this device, including the package label, must state that there are labeling limitations. The package insert must prominently state that the device system using pedicle screws is intended only for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar - first sacral (L5-S1) vertebral 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.
2. You may not label or in anyway promote this device system for pedicular, screw fixation/attachment to the cervical, thoracic or lumbar vertebral column for intended uses other than severe spondylolisthesis, as described above. The package insert must include the following statements:

WARNINGS:

- When used as a pedicle screw system, this device system is intended only for grade 3 or 4 spondylolisthesis at the fifth lumbar - first sacral (L5-S1) vertebral joint.
- The screws of this device system are not intended for insertion into the pedicles to facilitate spinal fusions above the L5-S1 vertebral joint.
- Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
- Potential risks identified with the use of this device system, which may require additional surgery, include:
 - device component fracture,
 - loss of fixation,
 - non-union,
 - fracture of the vertebra,
 - neurological injury, and
 - vascular or visceral injury.

See Warnings, Precautions, and Potential Adverse Events sections of the package insert for a complete list of potential risks.

3. Any pedicular screw fixation/attachment for intended uses other than severe spondylolisthesis, as described by item 1, for this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulations under 21 CFR, Part 812. All users of the device for pedicular screw fixation/attachment for intended uses other than severe spondylolisthesis, as described above, must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conducting an investigation.
4. Any previous warning statements identified as part of previous 510(k) clearances or required by OC/Labeling and Promotion which stated that a component/system was not approved for screw fixation into the pedicles of the spine must be replaced by the warnings of items 1 and 2 above.

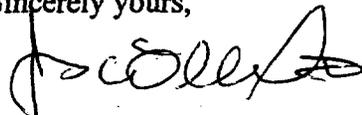
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

FDA advises that the use of your device system with any other device components but those identified in this 510(k) would require submission of a new 510(k) providing documentation of design, material, and labeling compatibility between the device components. Mechanical testing of a spinal system consisting of the subject device components and other device components, whether yours or those of other manufacturers, may also be required.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market.

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,


h 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

K97 3425

INTENDED USE

INDICATIONS FOR USE

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 - (b) anterior screw fixation to the cervical spine

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

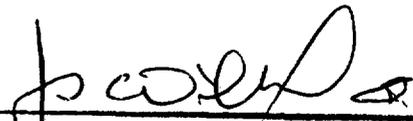
- (a) Degenerative disc disease of the lumbar thoracic and cervical spine relating to discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies.
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 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number 2973425

Prescription Use X
 (Per 21 CFR 801.109)

