

SEP 22 2003

**510(k) SUMMARY**

**Sponsor:** Highgate Orthopaedics  
One Walnut Street  
Boston, MA 02108

**Official Contact Person:** Kevin Connors, President

**Proprietary Trade Name:** Highgate Curved Rod System

**Device Description:** The Highgate Curved Rod System is available in titanium alloy (Ti6Al4V, ASTM F136) and includes rods and screws. Screws are used to attach the rod to the thoracolumbar spine. Rods are offered in two curvatures and have circular openings accommodate the screws.

**Intended Use:** The Highgate Curved Rod System is intended for unilateral screw fixation of the anterolateral thoracolumbar spine from T<sub>6</sub> to L<sub>5</sub> in skeletally mature patients. The Highgate Curved Rod System is intended to provide stabilization of a spinal segment as an adjunct to spinal fusion. Indications for the use of this device include spondylolisthesis (Grades 1 and 2), spinal stenosis, pseudarthrosis, failed fusion or degenerative disc disease (DDD) defined as back pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies. The Highgate Curved Rod System is **not** intended for patients having severe spondylolisthesis (Grades 3 and 4), deformities or curvatures, tumor or trauma i.e. vertebral fracture.

**Materials:** The Highgate Curved Rod System components are manufactured from titanium alloy (Ti6Al4V, ASTM F136).

**Substantial Equivalence:** Documentation was provided which demonstrated the Highgate Medial Curved Rods to be substantially equivalent to the previously cleared Highgate Lateral Curved Rods. The substantial equivalence is based upon equivalence in indications/intended use, manufacturing methods, interconnection mechanism, basic design, materials and testing.



SEP 22 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Kevin Connors  
President  
Highgate Orthopaedics  
One Walnut Street  
Boston, Massachusetts 02108

Re: K023983  
Trade Name: Highgate Curved Rod System  
Regulation Number: 21 CFR 888.3060  
Regulation Name: Spinal intervertebral body fixation orthosis  
Regulatory Class: II  
Product Code: KWQ  
Dated: September 5, 2003  
Received: September 8, 2003

Dear Mr. Connors:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

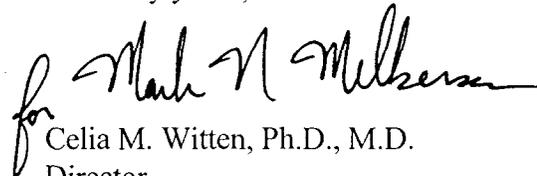
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

Page 2 - Mr. Kevin Connors

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Celia M. Witten". The signature is written in a cursive style and is positioned to the left of the typed name.

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

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use Statement

510(k) Number (if known): K023983

Device Name: **Highgate Curved Rod System**

Indications for Use:

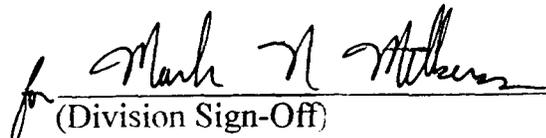
The Highgate Curved Rod System is intended for unilateral screw fixation of the anterolateral thoracolumbar spine from T<sub>6</sub> to L<sub>5</sub> in skeletally mature patients. The Highgate Curved Rod System is intended to provide stabilization of a spinal segment as an adjunct to spinal fusion. Indications for the use of this device include spondylolisthesis (Grades 1 and 2), spinal stenosis, pseudarthrosis, failed fusion or degenerative disc disease (DDD) defined as back pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies. The Highgate Curved Rod System is **not** intended for patients having severe spondylolisthesis (Grades 3 and 4), deformities or curvatures, tumor or trauma i.e. vertebral fracture.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR Over-the-Counter Use \_\_\_\_\_

  
(Division Sign-Off)

Division of General Restorative  
and Neurological Devices

510(k) Number K023983