

3. 510(k) Summary

Submitter	Synthes Spine 1230 Wilson Drive West Chester, PA 19380
Company Contact	Susan Lewandowski (484) 356-9614 lewandowskis@synthes.com
Name of the Device	Synthes Anterior Cervical Compression System
Predicate Device	Synthes Anterior Cervical Locking Plate - K031276
Device Description	<p>The Synthes Anterior Cervical Compression System consists of plates with cortical and cancellous screws. The plate attaches to the anterior portion of the vertebral body of the cervical spine (levels C2-C7).</p> <p>The implants of these systems are manufactured from Titanium Alloy (Ti-6Al-7Nb) and Elgiloy (40Co-20Cr-16Fe-15Ni-7Mo).</p>
Intended Use	Synthes Anterior Cervical Compression System is intended for anterior screw fixation to the cervical spine (C2-C7) for the following indications: Degenerative Disc Disease (DDD), spondylolisthesis, trauma (including fractures), spinal stenosis and tumors (primary and metastatic), failed previous fusions, pseudoarthrosis, and deformity (defined as kyphosis, lordosis or scoliosis).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 2004

Ms. Susan Lewandoski
Project Manager, Regulatory Affairs
Synthes Spine
1230 Wilson Drive
West Chester, Pennsylvania 19380

Re: K033844
Trade/Device Name: Synthes Anterior Cervical Compression System (ACCS)
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: December 9, 2003
Received: December 11, 2003

Dear Ms. Lewandoski:

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.

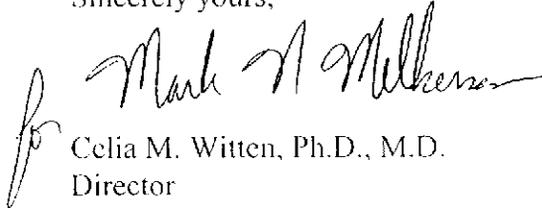
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 - Ms. Susan Lewandoski

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" (21 CFR 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 "Celia M. Witten". The signature is written in a cursive style and is positioned to the right of a vertical line that serves as a separator between the signature and 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

2. Indications for Use Statement

Special 510(k) Device Modification

INTENDED USE STATEMENT

510(k) Number (if known): K033844

Device Name: Synthes Anterior Cervical Compression System
(Modification to Synthes Anterior Cervical Locking Plate)

Indications Synthes Anterior Cervical Compression System is intended for anterior screw fixation to the cervical spine (C2-C7) for the following indications: Degenerative Disc Disease (DDD), spondylolisthesis, trauma (including fractures), spinal stenosis and tumors (primary and metastatic), failed previous fusions, pseudoarthrosis, and deformity (defined as kyphosis, lordosis or scoliosis).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

for Mark H. Melburn

Neurologica, Inc.

K033844