K022949

10.1 510(K) SUMMARY

MAR 2 4 2003

DESCRIPTION

Synthes USS, Click'X, USS VAS, Small Stature and Dual-Opening Systems are multi-component systems comprised of rods (5.0mm and 6.0mm), screws (side-opening, dual-opening and dual core) and hooks (side opening and dual opening), transconnectors, transverse bars, parallel connectors, collars, nuts, staples and washers.

INDICATIONS

Posterior Components

When used as posterior pedicle screw fixation system **in skeletally mature patients**, the Synthes USS, including the Click'X and USS VAS components, and the Dual-Opening USS and Synthes Small Stature USS (which includes small stature), is intended to provide immobilization and stabilization of spinal segments 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 (as defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, failed previous spinal fusion, and pseudoarthrosis.

When treating patient's with Degenerative Disc Disease (DDD), transverse bars are not cleared for use as part of the posterior pedicle screw construct.

In addition, **in skeletally mature patients**, the Synthes USS, including the Click'X and USS VAS components and the Dual-Opening USS and Small Stature USS (which includes small stature and pediatric patients) is intended for the treatment of severe spondylolisthesis (grade 3 and 4) of the L5-S1 vertebra in patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine with removal of the implants after the attainment of a solid fusion. The levels of pedicle screw fixation are L3-S2/ilium.

When used as a posterior non-pedicle screw fixation system, **in skeletally mature patients**, the Synthes USS, and the Dual-Opening and Small Stature USS (which includes small stature and pediatric patients) are intended for the treatment of degenerative disc disease (as defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease) fracture, pseudoarthrosis, tumor resection, and/or failed previous fusion.

Anterior Components

When used as an **anteriolateral** system, in **skeletally mature patients**, the Synthes USS, Dual-Opening USS and Small Stature USS (which includes small stature and pediatric patients), is intended for anteriolateral screw and/or staple fixation for the following indications: degenerative disc disease (as defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), fracture or dislocation of the thoracolumbar spine, pseudoarthrosis, tumor resection, and/or failed previous fusion (**levels T8-L5**).

In addition, when used with 3.5/6.0 mm parallel connectors, the Synthes USS can be linked to the CerviFix™ System. When used with 5.0/6.0 mm parallel connectors the Small Stature USS can be linked to the USS and Dual-Opening USS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2003

Ms. Vikki M. Hoffman
Senior RA Associate
Synthes Spine
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K022949
Trade Name: Synthes USS, Click'X, USS VAS, Dual-Opening USS and Small Stature USS
Regulation Number: 21 CFR 888.3070, 888.3060, and 888.3050
Regulation Name: Pedicle Screw Spinal System, Spinal Interlaminal Fixation Orthosis, and Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: III
Product Code: MNI, MNH, KWP, KWQ
Dated: December 23, 2002
Received: December 24, 2002

Dear Ms. Hoffman:

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.

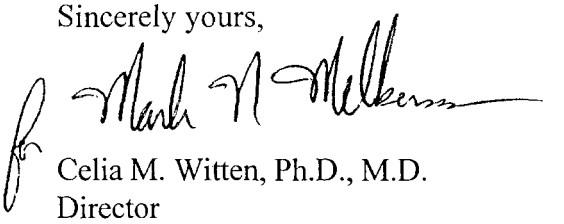
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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. 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,



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

3.0 FDA INDICATIONS FOR USE FORM

510(k) Number (if known): K022949

Device Name: Synthes USS, Click'X, USS VAS, Dual-Opening USS and Small Stature USS Systems

INDICATIONS FOR USE:

Posterior Components

When used as posterior pedicle screw fixation system **in skeletally mature patients**, the Synthes USS, including the Click'X and USS VAS components, and the Dual-Opening USS and Synthes Small Stature USS (which includes small stature), is intended to provide immobilization and stabilization of spinal segments 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 (as defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, failed previous spinal fusion, and pseudoarthrosis.

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Mark N Milhem

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K022949

Anterior Components

When used as an **anteriolateral** system, in **skeletally mature patients**, the Synthes USS, Dual-Opening USS and Small Stature USS (which includes small stature and pediatric patients), is intended for anteriolateral screw and/or staple fixation for the following indications: degenerative disc disease (as defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), fracture or dislocation of the thoracolumbar spine, pseudoarthrosis, tumor resection, and/or failed previous fusion (**levels T8-L5**).

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(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______

for Mark N Melkerson

(Divi[illegible] Sign-Off)
Divis[illegible] General, Restorative
and [illegible]ological Devices

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