K992739

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FEB 8 2000

Summary of Safety and Effectiveness Information [510(k) Summary]

SYNTHES (U.S.A.)
1690 Russell Road
Paoli, PA 19301

(610) 647-9700
Contact: Jonathan M. Gilbert
8/13/99

Device: Synthes USS, including Click'X components

The Synthes USS (including Click'X components) consists of rods, hooks, side-opening screws with collar and nut, variable axis screws with rod and screw connector, collar, locking ring and nut, transconnector systems, open and closed transverse bars, parallel connectors, Schanz screws, clamp with posterior nut and associated manual surgical instruments. The implants are composed of titanium (ASTM F1295, ASTM F67) or various grades of stainless steel.

The Click'X variable axis components of the USS system are composed of titanium (ASTM F1295, ASTM F67) and consist of rods, a transconnector system, pedicle screws, back-opening 3D Heads and Locking Cap. The back-opening 3D Head is clicked on the pedicle screw in situ and attaches to the rod with a locking cap. The locking cap consists of a ring to close the back-opening screw head and an inner set screw to fix the rod and the variable axis feature of the 3D Head.

The components of the predicate spinal system Synthes USS are currently marketed in the U.S. The indications for use, warnings and precautions for the subject components are similar to those cleared via K990745 and conform to labeling requirements set forth by 21 CFR 888.3070and FR Notice published 7/27/98 [Docket No. 95N-0176].

Posterior Components
When used as a posterior pedicle screw fixation system, the Synthes USS is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients 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 spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

In addition, the Synthes USS is intended for treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature 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 for these patients are L3-S2.

When used as a posterior non-pedicle screw fixation system, the Synthes USS is intended for scoliotic, lordotic, or kyphotic deformities (such as scoliosis, Schuermann's disease), degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), and fractures of the posterior thoracolumbar spine.

The Click'X components of the Synthes USS, when used as a posterior pedicle screw fixation system, are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, spinal tumor and failed previous fusion (pseudoarthrosis).

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In addition, when used with 3.5/6.0 mm parallel connectors, the Synthes USS can be linked to the CerviFix System.

Anterior Components
The Anterior Components of the USS are intended for anterolateral screw and/or staple fixation for the correction of anterolateral lordotic deformities for the spine, lumbar scoliosis, pseudoarthrosis, and fracture or dislocation of the thoracolumbar spine (levels T8-L5).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 8 2000

Mr. Jonathan M. Gilbert
Senior Regulatory Affairs Associate
Synthes Spine
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K992739
Trade Name: Click'X (to be used as part of the Universal Spinal System)
Regulatory Class: II
Product Code: MNH and MNI
Dated: November 10, 1999
Received: November 12, 1999

Dear Mr. Gilbert:

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.

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,

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

Page 1 of 1

510(k) Number (if known): NA K992739

Device Name: Synthes USS

Indications for Use:

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

Russell Fayn
(Division Sign-Off)
General Restorative Devices
510(k) Number K992739