K983766

DEC 18 1998

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

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

(610) 647-9700
Contact: James McCracken
10/23/1998

Device: SYNTHES SynMesh compared to the DePuy Motech Surgical Titanium Mesh (*K900138*).

The Synthes SynMesh consists of both flat mesh and preformed round and oval shaped mesh cylinders. The flat mesh is intended to be customized to a design and geometry that satisfies the patients anatomical defect. In addition, rings and screws are available to reinforce the cylinders. The preformed cylinders are offered in various sizes. The mesh and preformed cylinders are manufactured from commercially pure titanium (ASTM F67). Indication for use is in reinforcement of weak bony tissue in orthopedic surgical procedures.

The dimensions of the flat mesh are 90 x 112mm. The preformed cylinders are:

TYPE X(mm)	Y(mm)	Height Z(mm)
ROUND		
15		30
15		50
15		70
OVAL		
17	22	50
17	22	70
17	22	90
OVAL		
22	28	50
22	28	70
22	28	90
OVAL		
26	33	50
26	33	70
26	33	90
RING		
17	22	4.8
22	28	4.8
26	33	4.8
SCREW		
M3 x6.5	NA	NA

The range of dimensional characteristics of the SynMesh system is identical to the DePuy Motech Surgical Titanium Mesh. The hole to metal ratio of the SynMesh system falls within the range of hole to metal ratio of the DePuy Motech Surgical Titanium Mesh. Based on this information the mechanical characteristics fall within the range of mechanical characteristics of the DePuy Motech Surgical Titanium Mesh.

The SYNTHES SynMesh is indicated for the same clinical indications as that of the DePuy Motech Surgical Titanium Mesh.

Material composition is identical to the DePuy Motech Surgical Titanium Mesh. CP Titanium is an established biocompatible material.

This system is provided non-sterile; moist heat sterilization is recommended.

Based on the above, the SYNTHES SynMesh is substantially equivalent to the DePuy Motech Surgical Titanium Mesh.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 18 1998

Mr. James McCracken
Director, Regulatory, Clinical and Compliance
Synthes Spine
Post Office Box 0548
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K983766
Synthes SynMesh
Regulatory Class: II
Product Code: EZX
Dated: October 23, 1998
Received: October 26, 1998

Dear Mr. McCracken:

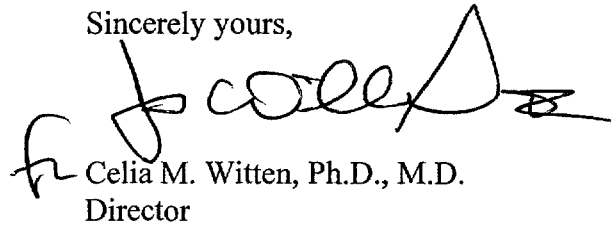
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 (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 requirements, 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" (21CFR 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 (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 and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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510(k) Number (if known): NA K983766

Device Name: SynMesh

Indications for Use:

Indication for use is for the reinforcement of weak bony tissue in orthopedic procedures.

(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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983766