JUL 25 2005

SYNTHES®

3.0 **510(k) Summary** K051720 Page 1 of 1

Sponsor:
Synthes (USA)
1302 Wrights Lane East
West Chester, PA 19380
(610) 719-5000

Device Name: Synthes (USA) Bone Marrow Aspiration (BMA) Syringe

Classification: Class II, 21 CFR §888.5860
Piston Syringe

Predicate Device: Merit Medical Systems, Disposable Coronary Control Syringe
Wright Medical Technologies, Bone Graft Syringe

Device Description: The syringe consists of a calibrated hollow barrel and a moveable plunger. At the distal end of the syringe there is a male connector nozzle for fitting the female connector (hub) of a single lumen needle. The syringe can be used for withdrawing body fluids.

Intended Use: The Synthes Bone Marrow Aspiration (BMA) Syringe is intended for aspiration of bone marrow, autologous blood, plasma, or other body fluids.

Substantial Equivalence: Documentation is provided which demonstrates that Synthes Bone Marrow Aspiration (BMA) Syringe is substantially equivalent* to other legally marketed devices.

*The term "substantial equivalence" as used in the 510(k) notification is limited to the definition of substantial equivalence found in the Food, Drug and Cosmetic Act, as amended and as applied under 21 CRF 807, Subpart E, under which a device can be marketed without pre-market approval or reclassification;. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2005

Ms. Kathy Anderson
Regulatory Affairs Manager
Synthes (USA)
1302 Wrights Lane East
West Chester, Pennsylvania 19380

Re: K051720
Trade/Device Name: Synthes (USA) Bone Marrow Aspiration (BMA) Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: June 23, 2005
Received: June 27, 2005

Dear Ms. Anderson:

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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson, MS
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SYNTHES®

2.0 **Indications for Use**

Indications for Use

510(k) Number (if known): K051720

Device Name: Synthes (USA) Bone Marrow Aspiration (BMA) Syringe

Indications:

The Synthes Bone Marrow Aspiration (BMA) Syringe is intended for aspiration of bone marrow, autologous blood, plasma, or other body fluids.

Prescription Use X AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K051720