ISOTIS
OrthoBiologics™

SEP 16 2004

K041991

510(k) Summary
for
IsoTis OrthoBiologics Aspirex™ - Bone Marrow Aspirate Kit

Sponsor

IsoTis OrthoBiologics, Inc.
2 Goodyear, Suite B
Irvine, CA 92618
U.S.A

Contact Person: Paul Doner
Telephone: (949) 855-7168
Facsimile: (949) 595-8711

Date Prepared: July 2004

Device Name

Proprietary Name: Aspirex™ - Bone Marrow Aspirate Kit
Common/Usual Name: Piston Syringe
Classification Name: Piston Syringe (Product Code FMF)

Predicate Devices

Proprietary Name: OrthoVita IMBIBE™ II Syringe (K030208)
Wright Medical Bone Graft Syringe (K023088)

Intended Use

Aspirex™ – Bone Marrow Aspirate Kit is for the aspiration of bone marrow, autologous blood, plasma or other blood components with or without prefilling with the surgeon's choice of bone void filler (allograft, autograft or synthetic bone graft material). The kit provides a convenient way to mix autologous blood or bone marrow with bone void filler and deliver to the orthopedic surgical site.

Device Description and Substantial Equivalence Rationale

The Aspirex™ - Bone Marrow Aspirate Kit contains two piston syringes: Aspirating Syringe and Infusion Chamber Syringe. These piston syringes along with a single lumen Aspirating Needle, Stylet, Luer-lock Adaptor, Cleaning Rod, Mixing Bowl and Spatula make up the components of the Aspirex™ Kit (will be packaged in various configurations, sizes, and quantities of these components).

The intended use, materials and design features of the Aspirex™ Kit syringes and components are similar to the predicate devices. Based on the above information, IsoTis OrthoBiologics considers the Aspirex™ - Bone Marrow Aspirate Kit to be substantially equivalent to the OrthoVita IMBIBE II Syringe and the Wright Medical Bone Graft Syringe.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 2004

Mr. Paul Doner
Manager, Regulatory Affairs
IsoTis OrthoBiologics
2 Goodyear, Suite B
Irvine, California 92618

Re: K041991
Trade Name: Aspirex™ Bone Marrow Aspirate Kit
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: II
Product Code: FMF
Dated: July 22, 2004
Received: July 23, 2004

Dear Mr. Doner:

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,

Miriam C. Provost

for 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

510(k) Number (if known):

Device Name: Aspirex™ - Bone Marrow Aspirate Kit

Indications for Use:

Aspirex™ – Bone Marrow Aspirate Kit is for the aspiration of bone marrow, autologous blood, plasma or other blood components with or without prefilling with the surgeon's choice of bone void filler (allograft, autograft or synthetic bone graft material). The kit provides a convenient way to mix autologous blood or bone marrow with bone void filler and deliver to the orthopedic surgical site.

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K041991