K041344

JUL 16 2004

510(k) Summary
for
IsoTis OrthoBiologics Open Bore Syringe

1. SPONSOR

IsoTis NV
Prof. Bronkhorstlaan 10
3723 MB Bilthoven
The Netherlands

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

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Date Prepared: May 2004

2. DEVICE NAME

Proprietary Name: Open Bore Syringe

Common/Usual Name: Piston Syringe

Classification Name: Piston Syringe (Product Code FMF)

3. PREDICATE DEVICES

Proprietary Name: OrthoVita Imbibe™ Bone Marrow Aspiration Syringe
Interpore Inducer Bone Graft Delivery Syringe

Common/Usual Name: Piston Syringe

Classification Name: Piston Syringe (Product Code FMF)

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4. DEVICE DESCRIPTION

The Open Bore Syringe is a standard piston syringe. It consists of a syringe barrel, piston and plunger. The distal end of the barrel is threaded to enable connection to three different adapters while without an attachment, the open end allows for filling of the bone graft material. Three distinct tips enable connection to a standard female Luer or dispensing through a tapered nozzle or extended tapered nozzle, and can be used depending on the viscosity of the bone graft material. A cap is available to seal the end of the barrel, enclosing the syringe contents. The piston/plunger assembly is used to expel from, or facilitate collection into the barrel.

5. INTENDED USE

The Open Bore Syringe is intended for use as a piston syringe for delivery of allograft, autograft or synthetic bone graft materials to an orthopedic surgical site. In addition it is designed to facilitate premixing of bone graft materials with autologous blood, plasma, platelet rich plasma, bone marrow aspirate as deemed necessary by the clinical use requirements.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Open Bore Syringe and the predicate devices are all similar in design, materials of construction and function as a piston syringe. All of the devices are provided sterile and non-pyrogenic for single patient use. The only difference between the proposed device and the predicate devices is in regard to the specific design configurations. The minor differences in design do not affect safety or effectiveness since all the devices carry out the same function. The safety and biocompatibility testing performed for and the long history of safe clinical use of piston syringes for delivery of bone grafts support the safe use of the Open Bore Syringe. The Open Bore Syringe also meets the requirements of ISO 7886-1 where applicable.

7. TESTING

The Open Bore Syringe is tested to conform to the recognized standard, ISO 7886-1 where applicable. Biocompatibility testing of the Open Bore Syringe has been performed to confirm that the device is safe. The devices to which the Open Bore Syringe claims substantial equivalence are the Orthovita Imbibe Bone Marrow Aspiration Syringe (K011087) and the Interpore Inducer Bone Graft Delivery Syringe (K972842) have been used safely for many years in the clinical environment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2004

IsoTis NV
c/o John F. Kay, Ph.D.
Chief Scientific Officer
IsoTis OrthoBiologics
2 Goodyear
Irvine, California 92618

Re: K041344
Trade/Device Name: Open Bore Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: II
Product Code: FMF
Dated: May 18, 2004
Received: May 25, 2004

Dear Dr. Kay:

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,

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): K041344

Device Name: Open Bore Syringe

Indications for Use:

The Open Bore Syringe is intended for use as a piston syringe for delivery of allograft, autograft or synthetic bone graft materials to an orthopedic surgical site. In addition it is designed to facilitate premixing of bone graft materials with autologous blood, plasma, platelet rich plasma, bone marrow aspirate as deemed necessary by the clinical use requirements.

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

for Mark N Milhouse

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

510(k) Number K041344