APR 16 2003

510(k) Summary

IMBIBE II Syringe

Submitted by	Address	Telephone	Contact Person
Orthovita, Inc.	45 Great Valley Parkway Malvern, PA 19355	(610) 640-1775	Andreina Ide Sr. Director, Regulatory Affairs

April 2001	Subject Device	Predicate Device
Trade Name	IMBIBE II Syringe	IMBIBE Bone Marrow Aspiration Syringe
Common Name	Bone Graft/Bone Void Filler Delivery Syringe	Bone Graft/Bone Void Filler Delivery Syringe
Classification Name	Piston Syringe	Piston Syringe

Device Description:

The IMBIBE II Syringe consists of a calibrated hollow barrel and a moveable piston. At the distal end of the syringe, there is a Luer-lock nozzle for fitting the connector (hub) of a single lumen aspiration needle. A Luer-lock nozzle makes a stable connection between the syringe and needle. A threaded screw cap (containing the Luer-lock nozzle) at the distal end of the syringe can be removed to allow the user to fill the syringe with his or her choice of bone void filler. The proximal end of the syringe contains a moveable piston. A Luer-lock nozzle is located in the center of the piston. This connector provides a mechanism for either of two actions.

- Fitting the male connector of a vacuum application device, such as a secondary empty piston syringe.
- Fitting the male connector of a secondary pre-filled piston syringe containing bone marrow, autologous blood, plasma or other blood components.

Prior to use, the IMBIBE II syringe is filled with the surgeon's choice of bone void filler (allograft, autograft or synthetic bone graft material). Two methods can be used to imbibe the bone void filler with bone marrow or autologous blood. Method I collects blood or marrow by way of a needle attached to the distal Luer-lock and vacuum/aspiration applied by way of a secondary syringe attached to the proximal Luer-lock. Method II fills the IMBIBE II Syringe through the proximal port (Luer-lock) with blood or marrow collected by way of a secondary syringe.
Once the desired volume of blood or marrow has been collected and mixed with the bone void filler, the secondary syringe and/or aspiration needle are removed. A pushrod is

attached to the piston at the proximal end of the IMBIBE II Syringe by way of the female Luer-lock, the distal cap is unscrewed and the contents of the syringe are delivered to the surgical site by extruding the mixed bone void filler.

Intended Use:

The IMBIBE II Syringe is intended for use as a piston syringe for the aspiration of bone marrow, autologous blood, plasma or other blood components. Prior to use, the syringe is filled with the surgeon's choice of bone void filler (allograft, autograft or synthetic bone graft material). This syringe provides the surgeon with a convenient way to mix blood or marrow with bone void filler (bone graft) and deliver the material to the orthopaedic surgical site.

Comparison to Predicate:

COMPARISON TO PREDICATE
Table I

	IMBIBE II Syringe	Predicates: IMBIBE Bone Marrow Aspiration Syringe K011087
Syringe Type	Piston Syringe	Piston Syringe
Intended Use	To collect blood components/bone marrow for mixing with bone graft and subsequent delivery to the surgical site.	To collect blood components/bone marrow for mixing with bone graft and subsequent delivery to the surgical site.
Principle of Operation	▪ Syringe used to collect blood, marrow ▪ Removable cap allows syringe to be filled with graft material ▪ Syringe provides for mixing of blood, marrow with graft material ▪ Removable screw cap allows for delivery of blood, marrow filled graft to surgical site ▪ Luer-lock (nozzle) at the proximal end of the barrel allows connection of a secondary piston syringe.	▪ Syringe used to collect blood, marrow ▪ Removable cap allows syringe to be filled with graft material ▪ Syringe provides for mixing of blood, marrow with graft material ▪ Removable screw cap allows for delivery of blood, marrow ▪ filled graft to surgical site

Overall Length	3.5, 4.6, 3.9, 5.3 inches (respectfully for a 5cc, 10cc, 15cc, 30cc internal volume)	2.9 inches
Barrel Diameter	,0.73, 0.73, 1.05, 1.05inches, OD (respectfully for a 5cc, 10cc, 15cc, 30cc internal volume)	0.73 inches, OD
Tip Type	Gasket	Gasket
Volume	5, 10, 15, 30 cc	10 cc
Nozzle Type	Luer-lock	Luer-lock
Barrel Markings	Graduated scale	Graduated scale
Lubricant Composition	None	Silicone
Lubricant amt/cm²	Not Applicable	100mg ± 5mg
Barrel Transparency	Transparent, no radiopacifiers	Transparent, no radiopacifiers
Reuse	Single use only	Single use only
Biocompatibility	Established by way of legally marketed device, IMBIBE Bone Marrow Aspiration Syringe, K011087 and ISO 10993 testing of adhesive	Established
Materials	Polycarbonate, ABS, Silicone, Dymax UV adhesive 1187-M-T	Polycarbonate, ABS, Silicone
Labeling	See Exhibit B. Same as predicate except additional information regarding directions for use.	See Exhibit C
Sterility	Sterilized by gamma radiation	Sterilized by gamma radiation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Andreina Ide
Senior Director, Regulatory Affairs
Orthovita, Inc.
45 Great Valley Parkway
Malvern, Pennsylvania 19355

Re: K030208
Trade/Device Name: IMBIBE II Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: II
Product Codes: FMF
Dated: January 17, 2003
Received: January 21, 2003

Dear Ms. Ide:

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. 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 Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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

INDICATIONS FOR USE STATEMENT

510(k) Number: K030208

Device Name: IMBIBE II Syringe

Indications For Use:

The IMBIBE II Syringe is intended for use as a piston syringe for the aspiration of bone marrow, autologous blood, plasma or other blood components. Prior to use, the syringe can be filled with the surgeon's choice of bone void filler (allograft, autograft or synthetic bone graft material). This syringe provides the surgeon with a convenient way to mix blood or marrow with bone void filler (bone graft) and deliver the material to the orthopaedic surgical site.

PLEASE DO NOT WRITE BELOW THIS LINE
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ℞ **OR** Over-The-Counter Use _____
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030208