K971114

510(k) Summary

JUN - 3 1997

Information as required by 21 CFR 807.92 is provided:

(1) Submitter Information

BioAccess, Inc.
4000 Hudson Street
Baltimore, MD 21224
410-675-8586 (Voice)
410-276-0217 (Fax)
Contact Person: Peter J. Carnes
Summary Prepared on: 26 March 1997

(2) Classification Name: Surgical instrument motors and accessories/attachments.

Common or Usual Name: Marrow Harvest aspiration needle or trephine

Proprietary Name: BioAccess Marrow Harvest System

(3) The predicate devices are:

- BioAccess Bone Marrow Harvest Kit - 510(k) K953064 - never commercially distributed by BioAccess, Inc.
- Jamshiti Aspiration needle - a pre-1976 device commercially distributed by Pharmaseal division of Baxter International.
- Disposable "J" Type Bone Marrow Biopsy/Aspiration Needle - 510(k) K843830 - commercially distributed by Popper & Sons. Inc.
- Hall Versipower Surgical Instrument System - 510(k) K895198 - know as the CORB System formerly commercially distributed by Zimmer, Inc., discontinued due to poor sales performance.

(4) The device is a hand-held battery powered device that penetrates the bone and allows aspiration through a hole in the bit for bone marrow harvest. The device is made from medical grade components and sold as a disposable procedure kit and a reusable motor unit.

(5) Penetration of the bone cavity and aspiration of marrow is the intended use of the device. The device has a more narrow intended use than the predicates as they are all for biopsy, coring and aspiration. This difference is not significant to safety or efficacy as it is a subset of the indications of the predicate.

(6) The device is similar in most ways to the predicates including but not limited to intended use, patient population, user population and materials. The significant difference between the BioAccess device and the predicates is the presence of battery power as an alternative to manual tools or AC power.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Peter J. Carnes
BioAccess, Inc.
8400 Cedar Street
Silver Spring, Maryland 20910

JUN - 3 1997

Re: K971114
Trade Name: BioAccess Marrow Harvest System
Regulatory Class: I
Product Code: GDM
Dated: March 26, 1997
Received: March 26, 1997

Dear Mr. Carnes:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4595. 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" (21 CFR 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/dsmamain.html".

Sincerely yours,

for 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

Page____of____

510(k) Number (if known): K971114

Device Name: BioAccess Marrow Harvest System

Indications For Use

The BioAccess Marrow Harvest System is indicated for the harvest of bone marrow from the pelvic bone cavity.

(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 Devices
510(k) Number K971114

Prescription Use X
(Per 21 CFR 801.109)

OR Over-The-Counter Use

(Optional Format 1-2-96)