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K111411

510(k) Summary - Freemie® Breast Pump Collection System

Submitter:	DAO Health 2526 Capitol Avenue Sacramento, CA 95816
Date Prepared:	May 18, 2011
Contact Person:	Dan Garbez Phone: 916-339-7388 FAX: 877-869-1973 e-mail: dan@daohealth.com
Device Trade Name	Freemie®
Device Common Name	Freemie® Breast Pump Collection System
Classification Name	Powered Breast Pump
Device Classification	Regulatory Class: Class II (two) Product Code: 85 HGX 884.5160
Predicate Device(s)	Medela® Pump in Style® Advanced Breastpump (K031614) Learning Curve Brands miPump™ (K082802)
Performance Standards	Performance standards have not been promulgated for powered breast pumps.
Intended Use	The Freemie milk collection system is intended to be used in conjunction with an approved electric breast pump for the purpose of expressing human milk.
Device Description	The device is to be used by connection to an approved breast pump, and will be used in place of the pump's original breast milk collection equipment. The device has a funnel-shaped breast adapter, internal valve assembly and enclosing reservoir shaped like a bowl. Variations of the device incorporate minor differences to replicate the functional and performance characteristics necessary for use with additional pump brands. Additionally, smaller and larger breast adapter and milk collection sizes will be available, as is the practice with predicate devices. The Freemie device is designed to be supported within a woman's ordinary or nursing brassiere, and held in place there while the lactating woman is pumping. When the pump extracts milk, the milk flows out through the end of the funnel and enclosing valve system, where it gathers and is collected in the cup. When the lactating woman is done pumping, she turns off the pump, removes the Freemie from her brassiere and transfers the milk to a storage container for later use.
Biocompatibility	The Freemie Breast Pump Collection System has passed all biocompatibility testing.

Performance Data	Performance testing was conducted to demonstrate Safety and Effectiveness and for comparison to the predicate device. Testing included: Breast Adapter Design, Compatible Pumps, Vacuum Performance and Capacity.
Summary	The Freemie Breast Pump Collection System is constructed of similar materials, has a similar design and the same indications as the Predicate Devices and other currently marketed accessories for powered breast pumps. Bench and biocompatibility testing have demonstrated equivalence and the safety and effectiveness of the device.
Conclusion	The Freemie Breast Pump Collection System is substantially equivalent to the predicate devices and other currently marketed accessories for powered breast pumps.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Dan Garbez
Manager
DAO Health
2526 Capitol Avenue
SACRAMENTO CA 95816

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Re: K111411
Trade/Device Name: Freemie® Breast Pump Collection System (Freemie)
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: January 24, 2012
Received: January 27, 2012

Dear Mr. Garbez:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K111411

Device Name: Freemie® Breast Pump Collection System (Freemie)

Indications for Use:

The Freemie breast pump collection system is intended to be used in conjunction with an approved electric breast pump for the purpose of expressing human milk.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-1-96)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111411