K101538

NOV - 5 2010

510(k) SUMMARY

510(k) Owner: Contact: Diana Korda Hewitt
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Date Summary Prepared: June 2, 2010

Device:

Trade Name:	Philips Avent Manual Breast Pump
Common/Classification Name:	Nonpowered Breast Pump
Device Classification:	Class I
Product Code:	HGY
Classification Regulation:	21 C.F.R. § 884.5150

Predicate Devices: Ameda Hand Breast Pump (K823591)
ISIS IQ Uno Handheld Electronic Breast Pump, Model 101 (K052047)
Medela Manual Breast Pump (K828340)

Device Description: The Philips Avent Manual Breast Pump expresses and collects milk from the breast of a lactating woman. The device is designed to be reusable by a single user. The pump diaphragm is activated by a manual pivoting handle. The duckbill valve closes to prevent backflow and seal the device under negative pressure as the handle is depressed. The valve then relaxes to allow milk flow into the bottle between pump actuations. Pumping can only be performed on one breast at a time. The vacuum level can be adjusted to comfort by varying the speed and travel of the manual handle. The device is comprised of the manual breast pump parts and feeding bottle.

The Philips Avent Manual Breast Pump operates in one mode – manual. In the manual mode, the user controls the frequency and level of vacuum by varying the stroke/cycle of the control handle lever.

All milk-contacting and human tissue-contacting components are manufactured from materials that meet the appropriate regulations regarding food contact and/or biocompatibility.

Intended Use: The Philips Avent Manual Breast Pump is intended to express and collect milk from the breasts of a lactating woman.

Technological Characteristics:	The Philips Avent Manual Breast Pump is substantially equivalent to the predicate devices with regard to intended use and technological characteristics. There are no new questions of safety or effectiveness presented. All breast contacting materials meet biocompatibility regulations (ISO10993), and all milk contacting materials meet food contact regulations.
Biocompatibility Data	Cytotoxicity, irritation, and dermal sensitization studies conducted on user-contacting materials demonstrate that the Philips Avent Manual Breast Pump is not cytotoxic, irritating, or a dermal sensitizer.
Performance Testing	The Philips Avent Manual Breast Pump and the predicated devices were measured for pressure in use as per their directions for use and worse use as well. All devices were tested using the same testing protocol. **Recommended Use Testing** The recommended use was **with** the cushion/inserts in place – as is instructed in the directions for use of the devices. The maximum pressure recorded with the cushion/inserts in place was an average of -249mmHg with the top outlier of -258.9mmHg for the Philips Avent Manual Breast Pump. The ISIS iQ UNO Handheld Breast Pump (K052047) predicate device was -248mmHg with the top outlier of -254.5mmHg. The Ameda One Handed Manual Pump Kit (K823591) was -288.3mmHg with a top outlier of -312.7mmHg. **Worse Case Use Testing** The worse case testing was **without** the cushion/inserts in place. This allows the breast/nipple to travel further down the tube reducing the dead volume and therefore increasing vacuum. The pressure recorded for the Philips Avent Manual Breast Pump was an average of -328mmHg and a top outlier of -338.8mmHg. The ISIS iQ UNO Handheld Breast Pump (K052047) predicate device in worse case use testing was -333mmHg with the top outlier of -337.5mmHg. The Ameda One Handed Manual Pump Kit (K823591) was -272.4mmHg with a top outlier of -282.5mmHg. Vacuum testing of the Philips Avent Manual Breast Pump and its predicate devices indicate that the average maximum vacuum pressures of all of these pumps range from approximately -240 to -300 mmHg under normal use and under worst case conditions do not exceed 350mmHg. This is due to the component architecture and design of the pump.
Conclusions	Based on the biocompatibility and nonclinical performance testing, it is concluded that the Philips Avent Manual Breast Pump is safe and effective for its intended use, and is substantially equivalent to the named predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Diana Korda Hewitt
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NOV - 5 2010

Re: K101538
Trade Name: Phillips AVENT Manual Breast Pump
Regulation Number: 21 CFR §884.5150
Regulation Name: Nonpowered breast pump
Regulatory Class: I
Product Code: HGW
Dated: November 1, 2010
Received: November 1, 2010

Dear Ms. Hewitt:

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,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K101538

Device Name: Philips Avent Manual Breast Pump

Indications for Use: The Philips Avent Manual Breast Pump is intended to express and collect milk from the breasts of a lactating woman.

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

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 Reproductive, Abdominal and Radiological Devices
510(k) Number K101538