

8 510(k) Summary

8.1 Submitter Name, Address, and Contact Information

Submitter: Avent America, Inc.
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8.2 Summary Preparation Date

This 510(k) summary was prepared on July 28, 2005.

8.3 Name of Device

The trade name of the device is the ISIS iQ UNO Handheld Electronic Breast Pump. The common name is Powered Breast Pump. The classification name is Powered Breast Pump.

8.4 Name of Predicate Device

Medela Pump In Style Advanced Breast Pump, by Medela Inc., K031614; and
Natural Comfort/Easy Comfort Battery/Electric Breast Pump, by The First Years, K032566.

8.5 Description of Device

The ISIS iQ UNO Handheld Electronic Breast Pump is a safe and effective powered breast pump used for expressing and collecting breast milk from the breasts of a lactating woman. The diaphragm within the pump is activated by a 6V DC electric motor controlled by a microprocessor. The device is comprised of a vacuum pump, 6V DC power supply, hand controller, Avent ISIS standard manual breast pump parts, and feeding bottles. The hand controller is designed to replicate the handle of the Avent standard manual ISIS Breast Pump, and is used to control the frequency and level of vacuum. A sealed AC/DC transformer or a battery pack powers the ISIS iQ UNO Breast Pump.

The ISIS iQ UNO Handheld Electronic Breast Pump operates in two modes. In the manual mode, the user controls the frequency and level of vacuum by varying the stroke/cycle of the control handle lever. After a comfortable manual pumping cycle has been established, the user engages the automatic pumping mode by depressing the control button on the hand controller. In the automatic mode, the pumping cycle is stored and controlled by the microprocessor. The user can switch between the automatic mode and manual mode at any time by repeatedly depressing the control button.

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

8.6 Intended Use of the Device

The ISIS iQ UNO Breast Pump is intended to express and collect milk from the breasts of a lactating woman.

8.7 Summary of Technological Characteristics

The technology of the ISIS iQ UNO Breast Pump differs slightly from the Medela predicate device. The ISIS iQ UNO provides total user control of the vacuum cycle and the ability to change between manual and automatic pumping. The Medela predicate device is programmed to deliver two pre-programmed pumping cycles in an automatic mode only, and allows the user to have limited control of pump operation. The Medela predicate device is programmed to change from a high frequency pumping cycle (let-down mode) to a lower frequency pumping cycle (expression mode) two minutes after power has been applied ("Natural Expression" technology). The user can change the pump cycle only from the let-down mode to the expression mode at any time during the first two minutes of operation. The user can vary the vacuum level during either operational mode.

The technology of the ISIS iQ UNO Breast Pump differs slightly from the First Years predicate. The First Years predicate features a fully automatic auto-nursing cycle consisting of a one-second suction and release. A dial knob on the pump handle controls the suction level.

The ISIS iQ UNO also differs slightly from the Medela predicate in the technology employed to achieve let-down and milk flow. The Medela predicate device employs "Natural Expression" technology described above to stimulate let-down and milk flow. The ISIS iQ UNO employs a patented let-down massage cushion designed to massage the area around the nipple in addition to allowing the user to control the frequency of the pumping cycle to stimulate let-down. The First Years predicate is similar to the ISIS iQ UNO regarding how let-down is stimulated. Both products employ a soft-textured breast shield.

The ISIS iQ UNO and both predicates operate with a sealed AC/DC transformer or with batteries.

The technological differences described above do not raise new concerns regarding the safety and effectiveness.

8.8 Summary of Non-clinical Performance Data

The ISIS iQ UNO meets all applicable electrical, mechanical, and environmental performance requirements given in the IEC 60601-1: 1998 + A1: 1991, A2: 1995, Corrigendum: 1994; ANSI/UL 60601:2003; EN-60601-1-1: 1990 + A1: 1993, A11: 1993, A12: 1993, A2: 1995, A13: 1996, Corrigendum: 1994; CAN/CSA C22.2 No. 601.1 issued: 1994/01/05 Rev: 1997/01/01; EN60601-1-2: 2001; and FCC Part 15 for a class B device. Additionally, all milk-contacting and human tissue-contacting components are manufactured from materials that meet the appropriate regulations regarding food contact and/or biocompatibility.

8.9 Summary of Clinical Performance Data

No clinical studies were performed.

8.10 Conclusion

Based upon the information presented in this dossier, it is concluded that the ISIS iQ UNO is safe and effective for the intended use, and is substantially equivalent to the predicate device.



SEP 22 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Avent America, Inc.
% Mr. Richard Morroney
Vice President
Clinivation, Inc.
One Speen Street, Suite 160
FRAMINGHAM MA 01701

Re: K052047
Trade/Device Name: ISIS iQ UNO Handheld
Electronic Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: July 29, 2005
Received: July 29, 2005

Dear Mr. Morroney:

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 (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 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052047

Device Name: ISIS iQ UNO Handheld Electronic Breast Pump

Indications For Use:

The ISIS iQ UNO Handheld Electronic Breast Pump is intended to express and collect milk from the breasts of a lactating woman.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(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)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K052047

Page 1 of _____