Section 5: 510(k) Summary

1.0 **Submitted By:**

Simplisse Inc.
4433 Fyler Ave.
St. Louis, MO 63116
Establishment Registration Number: None

JUL 14 2010

Primary Contact:
Glen Feye, President
Accurate Consultants, Inc.
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San Diego, CA 92103
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2.0 **Date Submitted:**

November 30, 2009

3.0 **Device Name(s):**

3.1 **Trade Name:**

Simplisse Electric Breastfeeding Companion

3.2 **Common Name:**

Powered Breast Pump

3.3 **Classification Name**

Electric Breast Pump (21CFR 884.5160, Product code - HGX)

4.0 **Predicate Devices:**

Candidate	Predicates	Manufacturer	Docket Number
Simplisse Electric Breastfeeding Companion	Medela's Pump In Style	Medela Inc.	K950750
	Ameda-Egnell Purely Yours	Ameda Medizintechnik AG	K973501
	Even Flo Comfort Control	Evenflow Co., Inc.	K983776

5.0 **Intended Use:**

The Simplisse Electric Breastfeeding Companion is a personal use electric powered device used to express milk from the breast of lactating women. The device is not intended for hospital use

6.0 **Comparison to Predicate Devices:**

The following table summarizes the basic similarities and differences between the candidate- Simplisse Electric Breastfeeding Companion and the predicates identified in Section 4.0 of this 510(k) Summary section.

Characteristic	Candidate	Predicates		
Name	**Simplisse Electric Breastfeeding Companion**	**Medela Pump In Style**	**Ameda-Egnell Purely Yours**	**Even Flo Comfort Control**
510(k) No.	None	K950750	K973501	K983776
Intended Use	To Express Milk	To Express Milk	To Express Milk	To Express Milk
Materials -21 CFR Parts 176, 177, and 178 compliant.	Yes	Yes	Yes	Yes
Power Source	1. AC Power Cord	1. AC Power Cord	1.AC Power Cord 2.6 AA Batteries	1. AC Power Cord 2. 12 V Car Adapter
Control Mechanism	Microprocessor	Mechanical	Microprocessor	Mechanical
Pump Type	Reciprocating Piston	Reciprocating Diaphragm	Reciprocating Piston	Reciprocating Diaphragm

Single or Double Breast Pumping	Both	Both	Both	Both
Adjustable Suction Levels	Yes	Yes	Yes	Yes
Adjustable Cycle Speed	Yes	Yes	Yes	Yes
Overflow Protection	Yes	No	Yes	Yes
Breast Cup-to Breast Interface	Thermoplastic Elastomer and Rigid Plastic	Rigid Plastic	Rigid Plastic (Partial Silicone covering available)	Rigid Plastic
Active Breast Massage	Yes	No	No	No
Weight	4-5 pounds	7-8 pounds	5-6 pounds	3-5 pounds

Design and Materials

All milk and human contact components from the Simplisse Electric Breastfeeding Companion and the predicates are manufactured from materials that meet FDA food additive criteria as set forth in Part 21 Code of Federal Regulations Parts 176, 177, and 178. In addition, the Breast Cup has been tested for biocompatibility per established guidelines.

7.0 Summary of Non-Clinical Performance Data:

Testing of the device has demonstrated that the Simplisse Electric Breastfeeding Companion meets established requirements when used in the manner and environment specified in product labeling.

8.0 Conclusion:

The Simplisse Electric Breastfeeding Companion is substantially equivalent to its predicate devices. Based upon the test data submitted, the device provides sufficient vacuum pressure to safely and effectively express and collect milk from lactating women.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Simplisse Inc.
c/o Mr. Glen Feye
President
Accurate Consultants, Inc.
1340 West Pennsylvania Ave.
SAN DIEGO CA 92103

JUL 14 2010

Re: K093648
Trade Name: Simplisse Electric Breastfeeding Companion
Regulation Number: 21 CFR §884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: July 7, 2010
Received: July 9, 2010

Dear Mr. Feye:

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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ATTACHMENT 1

Section 4: Indications for Use Statements

Indications for Use

510(k) Number (if known):

Device Name: **Simplisse Electric Breastfeeding Companion**

Indications for Use:

A personal use electric powered device used to express milk from the breast of lactating women.

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Reproductive, Abdominal, and
Radiological Devices
510(k) Number K093648