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the first years®

Ideas Inspired by Parents

Simplicity ™ Electric/Battery Breast Pump Kit

Section VII

510(k) Summary of Safety and Effectiveness Information

A. Submitter Information

Submitter's Name:	Anthony Paolo
Address:	The First Years, Inc. One Kiddie Drive Avon, MA 02322-1171
Telephone No.	508-588-1220, Ext. 234
Fax No.	508-583-9067
Contact Person:	Anthony Paolo
Date of Preparation:	October 31, 1996

B. Device Name

Trade Name:	**Simplicity** Electric/Battery Breast Pump Kit
Common/Usual Name:	Powered Breast Pump
Classification Name:	Powered Breast Pump

C. Predicate Device Name

Trade Name:	Evenflo Sof-Touch Ultra Breast Pump

D. Device Description

The Simplicity Breast Pump uses a mechanical pumping system to generate suction. It is powered either by two (2) standard C batteries (not included with kit) or powered electrically by utilizing the AC adapter which is provided in the kit and can be plugged into any standard wall outlet. The powered motor activates movement of a rubber diaphragm inside a pumping chamber which provides suction to express breast milk.

E. Intended Use of the Device

The powered Simplicity Breast Pump is designed to express milk from the breast.

F. Summary of Similarities and Differences

The 510(k) Substantial Equivalence Decision-Making Process (Detailed) decision tree (ODE Guidance Memo #K86-3) was utilized to make a determination of substantial equivalence (see Exhibit VII-I). The answers to the following questions from this decision tree lead to a determination of substantial equivalence:

Corporate Headquarters One Kiddie Drive, Avon, MA 02322-1171 **Tel** 508-588-1220 **Fax** 508-583-9067
Offices and Warehouses Fontana, California • Mississauga, Canada • Cirencester, UK • Gent, Belgium • Paris, France

1. **Does New Device have Same Indication Statements?**

   Yes. Although the unit labels from both the Simplicity Breast Pump and the Predicate [Evenflo] do not specifically set out its intended use, it is clear from the description of each that the intended use of both devices are to express milk from the breast and, therefore, are identical.

2. **Does New Device Have the Same Technological Characteristics, e.g., Design, Materials, etc.**

   No. Though the two systems have the same basic components (i.e., power source, pump, breast shields), the design of these components may vary. However, both systems are provided non-sterile and have been designed to contain a powered breast pump for reusable use.

   Both the Predicate [Evenflo] and the proposed **Simplicity** Breast Pump are powered by either electricity or batteries. However, the materials of manufacture may be different and some of the internal pumping components may differ. The **Simplicity** Breast Pump is designed for either dual sided action or single-sided pumping action.

3. **Could the New Characteristics Affect Safety or Effectiveness?**

   Yes. The differences between the proposed **Simplicity** Breast Pump and the Predicate [Evenflo] could affect both safety and effectiveness.

4. **Do the New Characteristics raise New Types of Safety or Effectiveness Questions?**

   No. Powered breast pumps, such as the proposed **Simplicity** Breast Pump and the Predicate [Evenflo] are generally intended to provide a means to express breast milk. The safety and effectiveness questions are not new and include questions concerning vacuum pressure as a function of time.

5. **Do Accepted Scientific Methods Exist for Assessing Effects of the New Characteristics?**

   Yes. The assessment of the effects of the characteristics of the proposed Simplicity Breast Pump can be determined using relatively simple experimental methods for determination of vacuum pressures as a function of time.

6. **Are Performance Data Available to Assess Effects of New Characteristics?**

   Yes. Laboratory bench testing was performed to assess the effects of the new characteristics of the proposed **Simplicity** Breast Pump. These tests compared the proposed **Simplicity** Breast Pump against the Predicate [Evenflo]. The objective of the laboratory testing was to determine substantial equivalence

of the performance characteristics between the **Simplicity** Breast Pump and the Predicate [Evenflo]. Specific performance characteristics evaluated included assessment of the vacuum pressure as a function of time.

7. **Does Performance Data Demonstrate Equivalence?**

Yes. The test data demonstrates that the performance of the **Simplicity** Breast Pump in terms of vacuum pressure as a function of time is suitable for its intended use, and the device is substantially equivalent to the Predicate [Evenflo].

Conclusion:

Based on the FDA's decision tree, the subject device, the Simplicity Breast Pump, is substantially equivalent to the Predicate [Evenflo].

Contact Person: Anthony G Paolo

Anthony Paolo
Director-Quality Assurance

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