DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Recd 8-20-01
9T

AUG 1 5 2001

Mr. Joseph S. Tokarz
Manager, Regulatory Affairs
Hollister Incorporated
2000 Hollister Drive
LIBERTYVILLE IL 60048-3781

Re: K011519
Ameda HygieniKit
Dated: May 16, 2001
Received: May 17, 2001
Regulatory Class: II
21 CFR §884.5150/Procode: 85 HGY
21 CFR §884.5160/Procode: 85 HGX

Mr. Joseph S. Tokarz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

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

Enclosure (s)

Ameda HygieniKit Additional Claim

b. Statement of Intended Use

510(k) Number (if Known): K011519
Device Name: Ameda HygieniKit

Intended Use:

The Ameda HygieniKit is intended to be connected to a powered breast pump or adapted for use as a manual breast pump to express and collect the mother's milk of a nursing woman for the purpose of feeding the collected milk to a baby.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR
(Per 21 CFR 801.109)

Over-the-Counter-Use ✓
(Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011519

Hollister Incorporated
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Telephone: 847.680.1000
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Hollister

510(k) Summary

1. Sponsor's name, Address and Contact Person

Sponsor
Hollister Incorporated
2000Hollister Drive
Libertyville, IL
60048

Contact Person
Joseph S. Tokarz
Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048
Ph: (847)680-2849
Fax: (847)918-3860

Date Summary Prepared – May 16, 2001

2. Name of Device:
Ameda HygieniKit

3. Name of Predicate Device(s)
Ameda HygieniKit

4. Description of Device
The Ameda HygieniKit is used as an accessory with the Ameda manual and powered breast pumps to express milk from the breast. The HygieniKit incorporates in it's design a patented silicone diaphragm that creates a barrier protecting the pump and tubing from penetration of bacteria and viruses (Hepatitis B and C and Human Immunodeficiency Virus HIV) from contaminated liquids inside the collection bottle system.

Likewise, the diaphragm in this product creates a barrier protecting liquids collected in the collection bottle system from penetration of bacteria and viruses (Hepatitis B and C and Human Immunodeficeiency Virus HIV) from the pump and tubing in the event of contamination of these components during a prior use or by a prior user.

Note that the Ameda HygieniKit neither removes bacteria and viruses (Hepatitis B and C and Human Immunodeficiency Virus HIV) from the breast milk being collected into the collection bottle nor does the Ameda HygieniKit make it safe for infected mothers to feed their infants with milk collected using this device.

The Ameda HygieniKit breast pump kits consist of: a collection bottle, one way valve, pumpbody, silicone diaphragm, cap, and pump tubing. The device may also be supplied with a breast shield as an option. (See diagram in section d below) The mother connects the tubing contained in this kit to the suction apparatus of the Ameda manual or powered breast pumps. The mother can use one milk collection kit at a time or two of the same model to pump both breasts at once

5. Statement of Intended Use

The Ameda HygieniKit is used in conjunction with Ameda manual and powered breast pumps and are intended to express and collect the mother's milk from the breasts of a nursing woman, for the purpose of feeding the collected milk to a baby.

6. Statement of Technological Characteristics of the Device

The Ameda HygieniKit is used as an accessory with the Ameda manual and powered breast pumps to express milk from the breast. The HygieniKit incorporates in it's design a patented silicone diaphragm that creates a barrier protecting the pump and tubing from penetration of bacteria and viruses (Hepatitis B and C and Human Immunodeficiency Virus HIV) from contaminated liquids inside the collection bottle system.

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Issues of material biocompatibility have been submitted to and cleared by the Agency in a previous submission K912355/C.

The Ameda HygieniKit silicone diaphragm was tested by an independent laboratory for both its viral and bacterial barrier properties. These test were performed in accordance with the US FDA or US EPA Regulations and Good Laboratory Practice Regulations. The results of these tests indicated that the silicone diaphragm that is incorporated in the Ameda HygieniKit Collection system is an effective barrier against bacteria and viruses.

7. Conclusion

Based on information presented above and in the body of this premarket notification the Ameda HygieniKit with additional claim is substantially equivalent to devices currently in commercial distribution.