K052858

FEB 9 2006

Section 5

510(k) Summary

Soothies

Contact Person: Ms. Leslie Sebastian

Title: President and CEO

Address: 9853 Pacific Heights Boulevard; Suite L; San Diego, CA 92121

Phone: (858) 228-1660

Fax: (858) 228-1650

Email: Leslies@soothies.com

Establishment Registration Number: Pending

Regulation Number: Classification: 880.5630

Device Class: 1

Common Name, Device: Nipple Shield

Regulation Medical Specialty: General Hospital

Review Panel: General Hospital

Intended Use

Soothies Gel Pads are designed to enhance breastfeeding success by preventing friction between the nipple and the mother's clothing. They provide relief for sore and/or cracked nipples. Soothies are an absorbent and protective nipple shield. They provide a cooling sensation.

Description of Device

Soothies are a nipple shield and are composed of glycerin, water and polyacrylamide, with a cloth backing. The gel pads soothe painful nipples and provide a cooling sensation.

K052858

Predicate Devices

Soothies and ElastoGel Occlusive Gel are substantially equivalent because they are made of the same material.

Soothies are also substantially equivalent to the Ameda Comfort Gel Hydrogel Pads and the Breast Therapy Soothing Gel Patches because they have the:

- Same intended use
- Same indicated target population
- Same environment of use, and
- Same or similar design

Safety

The differences between Soothies and its predicate devices do not adversely affect the safety or effectiveness of the product. Although Soothies, the Ameda Comfort Gel Hydrogel Pads, and the Breast Therapy Soothing® Gel Patches contain some different materials, as described below, numerous studies have demonstrated the safety of Soothies.

Puronyx has had the safety of Soothies studied for any potential health risk to a nursing infant and mother attributable to acrylamide monomer in the acrylamide polymer gel component of Soothies. The evaluation assumes that a residue of acrylamide gel is present on the mother's breast following her use of the pad and is subsequently ingested by the infant. The evaluation demonstrates that the heath risks to a nursing infant and an adult woman using the pads are *de minimis*.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 9 2006

Ms. Leslies Sebastian
President and CEO
Puronxy, Incorporated
9853 Pacific Heights Boulevard, Suite L
San Diego, California 92121

Re: K052858
Trade/Device Name: Smoothies® Gel Pads
Regulation Number: 880.5630
Regulation Name: Nipple Shield
Regulatory Class: I
Product Code: NXH
Dated: January 25, 2006
Received: January 26, 2006

Dear Ms. Sebastian:

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.

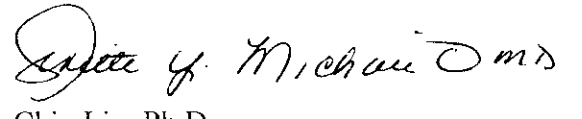
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K052858

Indications for Use

510(k) Number (if known): K052828

Device Name: Soothies® Gel Pads

Indications for Use: Soothies Gel Pads are designed to enhance breastfeeding success by preventing friction between the nipple and the mother's clothing. They provide relief for sore and/or cracked nipples.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

K052858