K022542
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PHILIPS

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Philips Consumer Electronics Company

510(k) Summary
(As required by 21 CFR 807.92)

Premarket Notification Number: _____

1. Submitter's Identification:

   Philips Consumer Electronics
   One Philips Drive, Knoxville, TN 37914
   Phone: (865) 521-4701
   Fax: (865) 521-3402
   Contact: Mr. Bob Pooler

   Date Summary Prepared: July 18, 2002

2. Name of the Device:

   Philips Baby Thermometer Set (SBC SC530)

3. Predicate Device Information:

   1) The Paci-Temp Pacifier Thermometer, K952073, Intelligent Products L.C., Orem, Utah (presently owned by Acute Ideas Co., Ltd.)
   2) The Pro-Flex Digital Thermometer with Flexible Probe, K961357, Intelligent Products L.C., Orem, Utah (presently owned by Acute Ideas Co., Ltd.)

4. Device Description:

   The Philips Baby Thermometer set allows parents to accurately and conveniently measure the baby's temperature. The baby thermometer set is designed for he baby's safety, comfort, well-being and, therefore, parents own peace of mind.

   The set contains three items:
   - A soother thermometer to reliably measure baby's temperature. It is very convenient to use both for parents and baby.

Philips Consumer Electronics Company
A Division of North American Philips Corporation
Product Safety and Compliance
One Philips Drive, P.O. Box 14810
Knoxville, TN 37914-1810

- An ordinary soother to let the baby get used to the shape. Parents can use this soother as a regular soother.
- A digital flexible-tip thermometer that measures baby's body temperature rectally if parents want added reassurance.

5. Intended Use:

The Philips Baby Thermometer Set is intended for determination of baby's temperature. The set contains three items:
- A pacifier thermometer to detect baby's oral temperature.
- An ordinary pacifier can be used as a daily used regular pacifier
- A digital flexible-tip thermometer to detect baby's rectal or underarm (axillary) temperature.

6. Comparison to Predicate Devices:

The Philips Baby Thermometer Set contains a pacifier thermometer and a digital flexible-tip thermometer which are substantially equivalent to the Paci-Temp Pacifier thermometer and Pro-Flex Digital Thermometer with Flexible Probe.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The Philips Baby Thermometer Set conforms to physical requirements and operating parameters outlined in ASTM1112, "Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature". It also meets EPA requirements for nitro-amines and Consumer Product Safety Commission (CPSC 1511) requirements for Baby Pacifiers (choking hazards).

8. Discussion of Clinical Tests Performed:

Clinical testing previously performed for the Paci-Temp and Pro-Flex also applies to the Philips Baby Thermometer Set.

9. Conclusions:

The Philips Baby Thermometer Set is substantially equivalent in intended use, design, material and technology to the Paci-Temp and Pro-Flex, which contains both of these items in one set. Thus, when compared to the predicate devices, the Philips Baby Thermometer Set does not incorporate any significant changes in intended use, method of operation, material, or design that could affect safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 0 2002

Mr. Robert Pooler
Manager, Product Safety & Compliance Division
Phillips Consumer Electronics
One Phillips Drive
Knoxville, Tennessee 37914

Re: K022542
Trade/Device Name: Philips Baby Thermometer Set (SBC SC530)
Regulation Number: 880.2910
Regulation Name:
Regulatory Class: II
Product Code: FLL
Dated: July 18, 2002
Received: August 1, 2002

Dear Mr. Pooler:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

for Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name : Philips Baby Thermometer Set (SBC SC530)

Indications For Use :

The Philips Baby Thermometer Set is intended for determination of a baby's oral, rectal, or axillary temperature.

The set contains three items:

- A pacifier thermometer to detect baby's oral temperature.
- An ordinary pacifier can be used as a daily use pacifier to help accustom the baby to the shape of the pacifier-thermometer.
- A digital flexible-tip thermometer to detect baby's rectal or underarm (axillary) temperature.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109

(Optional Format 1-2-96)

Patricia Cucente

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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