

NOV 2 1998

EXHIBIT #1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMMA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: _____.

1. Submitter's Identification:

Barchens Company
7F-4, No. 246, Sec. 2
Chang-An East Road
Taipai, Taiwan R.O.C.
Contact: Mr. Frank Hsieh

Date Summary Prepared: October 13, 1998

2. Name of the Device:

Barchens Digital Pacifier Thermometer

3. Predicate Device Information:

1. The Pro-Check™ Pacifier Digital Thermometer K#972259.
2. The Pasi-Temp Pacifier Digital Thermometer, K#952073, Intelligent Product Ltd. Co., Orem, Utah (presently owned by Acute Ideas Co., Ltd.)
3. The Basis® Baby-Temp Pacifier Digital Thermometer, K#962991, Polymedica Industries, Inc., Golden, Colorado

4. Device Description:

The Barchens Digital Pacifier Thermometer, is a battery-powered, liquid crystal display device using a thermometer embedded in the nipple. The patient contact portion is composed of medical silicone rubber. The body is of ABS plastic. This device is reusable and no components are disposable. This device is not intended for use with other sheaths or devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 28 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Barchens Company
C/O Ms. Susan Goldstein-Falk
Official Correspondent for Barchens Company
Mdi Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K983619
Trade Name: Barchens Company Digital Pacifier
Thermometer
Regulatory Class: II
Product Code: FLL
Dated: October 13, 1998
Received: October 15, 1998

Dear Ms. Goldstein-Falk:

This letter corrects our substantially equivalent letter of November 2, 1998, regarding the company name.

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.

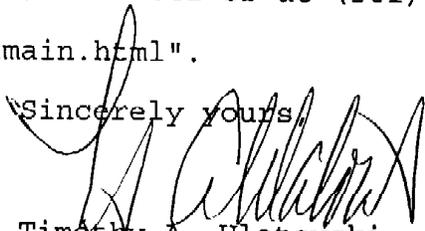
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug

Administration (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) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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

510(k) NUMBER (IF KNOWN): K983619

DEVICE NAME: The Barchens Digital Pacifier Thermometer

INDICATIONS FOR USE:

The Barchens Digital Pacifier Thermometer is a non-sterile, re-usable clinical thermometer intended for the determination of oral body temperature in infants to children five years of age.

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

Concurrent of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use
(Optional Format 1-2-96)

Patricia Crescent
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983619