

AUG 23 2000

K993950

510(k) Summary
As Required By 21 C.F.R. §807.92

1. The submitter of this premarket notification is:

James Delaney
EXPERTech Associates, Inc.
100 Main Street, Suite 120
Concord, MA 01742
Tel: 978.371.0066, Fax: 978.371.1676

This summary was prepared on July 5, 2000

2. The name of this device is the Cecilia® Penguin Multi-Use Thermometer. The classification name is as follows:

Regulation Number & ProCode	Classification Name
880.2910, 80 FLL	Clinical electronic thermometer

3. The Cecilia® Thermometer is substantially equivalent to the Braun Thermoscan® IRT 3020/3520 (K983295).
4. The Cecilia® Thermometer consists of an IR sensor, an electronic signal processing detector, a digital LCD display, and disposable probe covers.
5. The Cecilia® Thermometer has the same intended use as the legally marketed predicate device. The Cecilia® Thermometer is intended for intermittent measurement of body temperature in individuals of all ages in the home environment by measurement of infrared radiation emitted, solely, from the tympanic membrane.
6. The Cecilia® Thermometer and the predicate Braun Thermoscan® IRT 3020/3520 device both operate using the same IR measurement technology. The measurement technology, including the processing, transmission, and display of signals, are similar, and therefore the technological characteristics of the Cecilia® Thermometer are essentially the same as those of the legally marketed predicate device.
7. The Cecilia® Thermometer was subjected to safety and performance tests for compliance against applicable recognized standards. Additional testing activities were conducted to establish the performance and reliability characteristics of the device, including testing to establish laboratory and clinical accuracy.



AUG 23 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Nien Made Electrnics Corporation
C/O Mr. James M. Delaney
Expertech Associates, Incorporated
100 Main Street Suite 120
Concord, Massachusetts 01742

Re: K993950
Trade Name: Cecilia Penguin Multi-Use Thermometer,
Model HP-ETO9999
Regulatory Class: II
Product Code: FLL
Dated: July 10, 2000
Received: July 13, 2000

Dear Mr. Delaney:

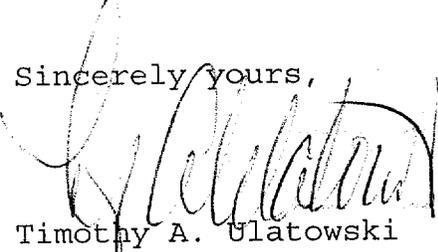
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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 (Pre-market 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 pre-market 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. 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,



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

Enclosure

Indications for Use Statement

510(k) Number
(if known)

K 99 3950

Device Name

Nien Made Electronics Corporation Cecilia®
Penguin Multi-Use Thermometer

Indications for
Use

Indications: For intermittent measurement of
body temperature in patients of all ages in the
home environment by measurement of infrared
radiation emitted, solely, from the tympanic
membrane.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

Pattina Concerde
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993950