

JAN 14 1999

510(k) Talking Digital Thermometer
K-Jump Health Co., Ltd.

510(k) Summary

Proprietary Name: Talking Digital Thermometer

Common Name: Digital Thermometer with Voice Feature

Classification: Class II

Submitter Details: Polygreen Company, Ltd.
a subsidiary of K-Jump Health Co. Ltd.
136 Wu Kung Road, Wu Ku Industrial Park
Taipei, Hsien
Taiwan, R.O.C.
Tele.: 001-886-2-2991378-82
Fax: 001-886-2-2991386
Contact: Mr. Tseng Chao Man (Daniel)

The Talking Digital Thermometer is a clinical thermometer intended for the determination of oral, rectal, and axillary body temperature determination in humans.

In terms of physical requirements and operating parameters, the thermometer conforms to ASTM E1112, "Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature."

The Talking Digital Thermometer is substantially equivalent to Polygreen Company, Ltd.'s Basis Digital Thermometer and Atico International's Walgreens Talking Thermometer.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 14 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

K-Jump Health Co., Ltd.
C/O Mr. Robert J. Zappa
President
PolyMedica Healthcare, Incorporated
720 Corporate Circle, Suite R
Golden, Colorado 80401

Re: K984553
Trade Name: Talking Digital Thermometer, Model KV-171
Regulatory Class: II
Product Code: FLL
Dated: December 21, 1998
Received: December 22, 1998

Dear Mr. Zappa:

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

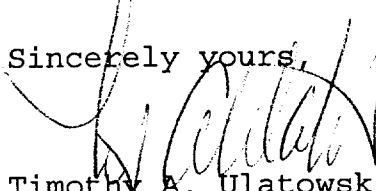
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

510(k) Talking Digital Thermometer
K-Jump Health Co., Ltd.

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(K) Number: Unassigned
K-Jump Health Co., Ltd.

Device Name: Talking Digital Thermometer

Indications for Use: The Talking Digital Thermometer is a non-sterile, reusable clinical thermometer intended for the determination of oral, rectal, and axillary body temperature determination humans.

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

Concurrence of CDRS, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

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

Patricia Cucchi

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

510(k) Number 1984553