

JAN 14 2000

K984551

510(k) Infrared Ear Thermometer
K-Jump Health Co., Ltd.

510(k) Summary

Proprietary Name: Infrared Ear Thermometer

Common Name: Radiation Thermometer (Tympanic Temperature)

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 Infrared Ear Thermometer is a clinical thermometer intended for the determination of human temperature by radiation emitted via the human ear (tympanic temperature).

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 Infrared Ear Thermometer is substantially equivalent to Becton Dickinson's Assure Ear Thermometer.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 2000

Jonathan S. Kahan, Esquire
Hogan & Hartson, L.L.P.
Columbia Square
555 Thirteenth Street N.W.
Washington, D.C. 20004-1109

Re: K984551
Trade Name: K-Jump Health Co., Ltd.'s Infrared Ear
Thermometer, Model KI-8120
Regulatory Class: II
Product Code: FLL
Dated: November 5, 1999
Received: November 5, 1999

Dear Mr. Kahan:

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 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 for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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

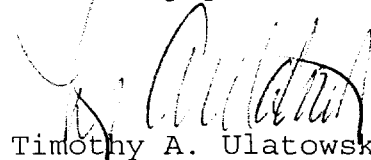
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obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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" (21 CFR 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/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) Infrared Ear Thermometer
K-Jump Health Co., Ltd.

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

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

Device Name: Infrared Ear Thermometer

Indications for Use: The Infrared Ear Thermometer is a non-sterile, reusable clinical thermometer intended for the determination of human temperature by radiation emitted via the ear (tympanic temperature).

(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 Cincotta
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K984551