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510(K) SUMMARY

ThermoTek™ IR Forehead Thermometer Model 718F

510(k) Number K 002712

Applicant's Name:

SAAT Ltd.
17 Nachshon Street.
Segula, Petach Tikva 49130, Israel
Tel.: 972-3-9050200
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Contact Person:

Shoshana Friedman, RAC
Push-med Ltd.
117 Ahuzah St.
Ra'anana 43373, Israel
Tel: 972-9- 7718130
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Date Prepared:

August, 2000

Trade Name:

ThermoTek™ IR Forehead Thermometer Model 718F

Classification Name:

Thermometer, Electronic, Clinical

Classification:

Class II; Product Code FLL; Regulation No.: 880.2910.

Statement of Substantial Equivalence:

The ThermoTek™ IR Forehead Thermometer Model 718F is substantially equivalent in all aspects, e.g., technological characteristics, modes of operation, performance characteristics, intended use, etc., to the commercially available E-Z-Therm IR Ear Thermometer. The main change between the two devices is the change in the measurement site (forehead instead of ear), which resulted in change of the soft tip, eliminating the need for probe cover, change in the software look up table to fit forehead temperature measurement, and change in the device name.

Device Description:

The ThermoTek™ 718F consists of an Infra Red forehead thermometer unit. The thermometer has an IR detector that detects the IR heat emission from the forehead, and a built-in CPU that converts the IR heat to equivalent oral temperature. The result is displayed on a LCD.
The LCD, push buttons, battery, microprocessor and the PCB are located in one housing which includes upper cover, lower cover and the battery cover. The entire device is compact, lightweight, easy to use and portable.

Indications:

The ThermoTek™ IR Forehead Thermometer Model 718F is a non-professional thermometer and is intended for body temperature measurement (oral equivalent) for home use only.

Performance Data:

A series of safety and performance testing demonstrated that the ThermoTek™ is substantially equivalent to the E-Z-Therm without raising new safety and/or effectiveness issues

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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S.A.A.T Limited
C/O Ms. Shoshana Friedman
Managing Director
Push-Med Limited
117 Ahuzah St.
Ra' Ananna,
ISRAEL

Re: K002712
Trade Name: ThermoTek™ IR Forehead Thermometer Model 718F
Regulatory Class: II
Product Code: FLL
Dated: November 14, 2000
Received: November 15, 2000

Dear Ms. Friedman:

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 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,

Susan Runner

for 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) Number (if known): K002712

Device Name: Thermo-Tek IR Forehead Thermometer

Classification Panel: 880.2910

Indications for Use:

The indication for use of the Thermo-Tek IR Forehead Thermometer is exactly the same indication for use as the E-Z-Therm IR Ear Thermometer (except for change in the measuring location).

The Thermo-Tek IR Forehead Thermometer is intended to measure body temperature from the site of the forehead and can be used in both the home setting and the professional setting.

(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** X

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002712