FEB 2 7 2001

510(k) Summary
ThermoTek™ Quickcare
510(k) Number K010502

Applicant's Name: SAAT Ltd.
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Fax.: +972-3-9345577

Contact Person: Mr. E.J. Smith
Smith Associates,
1468 Harwell Avenue
Crofton, Maryland 21114
Tel.: 410-451-0639
Fax.: 410-793-0448

Date Prepared: January, 2001

Trade Name: ThermoTek™ Quickcare

Classification:
Name: Thermometer, Electronic, Clinical.
Product Code: FLL
Regulation No.: 880.2910
Class: II
Panel: 80 (General Hospital)

Device Description

The device is an electronic non-predictive contact thermometer. It consists of a Chromium-plated commercial thermistor, a flexible tip and rigid plastic housing that contains a PCBA, a LCD and two flexible buttons (On and Memory). The device is operated on a single 1.5V Silver-Oxide battery. The thermistor reaches a thermal equilibrium with the measured subject in about 10 seconds, thanks to its small size.

Intended Use

The ThermoTek Quickcare is intended for taking body temperature orally, rectally or under the arm.

Performance Data

The ThermoTek Quickcare was tested in a series of safety and performance tests, showing its compliance with the relevant standards, without raising any safety and/or effectiveness issues.

Statement of substantial equivalence

The device is substantially equivalent to the following products in commercial distribution:

1. **Manufacturer**: Becton Dickinson & Co.
   Product Name: B-D Flexible Digital Thermometer, Model 524034
   510(k) No.: K902624
2. **Manufacturer**: Becton Dickinson & Co.
   Product Name: B-D Digital Thermometer, Model 403001
   510(k) No.: K935267
3. **Manufacturer**: Toshiba Glass Co., LTD.
   Product Name: Toshiba Digital Clinical Thermometer, Model ME-171B
   510(k) No.: K881909

The device defers from these cleared products mainly by its short response time, which is about 10 seconds.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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SAAT Limited
C/O Mr. Ned Devine Jr.
Responsible Third Party Official
Entela, Incorporated
3033 Madison Avenue, Southeast
Grand Rapids, Michigan 49548

Re: K010502
Trade Name: ThermoTek™ Quickcare
Regulatory Class: II
Product Code: FLL
Dated: January 15, 2001
Received: January 21, 2001

Dear Mr. Devine:

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,

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

510(k) Number (if known) _____

Device Name: ThermoTek™ Quickcare

Indications for Use:

The **ThermoTek Quickcare** is intended for taking body temperature orally, rectally or under the arm.

(Please do not write below this line - continue to another page if needed)

510(k) Number K010502

Prescription Use _____ Or Over the counter use ✓
(Per 21 CFR 801.109)

Victoria Cuevas

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010502