JUL 2 2 2004

510(k) Summary
ThermoTek™ Q5
510(k) Number K041646

Applicant's Name: SAAT Ltd.
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Segula, Petach Tikva, 49277, Israel
Tel.: +972-3-9050200
Fax.: +972-3-9345577

Contact Person: Mr. E.J. Smith
Smith Associates,
1468 Harwell Avenue
Crofton, Maryland 21114
Tel.: 410-451-0639
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Date Prepared: January 27 , 2004

Common Name: Oral Thermometer

Trade Name: ThermoTek™ Q5

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 contact thermometer. It consists of a commercial thermistor in a stainless steel cap, a tip and rigid plastic housing that contains a PCBA, a LCD and two flexible buttons (On and Mode). The device is operated on a single 3V Lithium battery. Thanks to its small size, the thermistor reaches a thermal equilibrium with the measured subject in about 5 seconds in a bath and in oral and rectal modes, and in about 20 sec in axial mode,.

Intended Use

The ThermoTek Q5 is intended for taking body temperature orally, rectally or under the arm.

Performance Data

The ThermoTek Q5 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.

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Statement of substantial equivalence

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

1. **Manufacturer:** SAAT Ltd.
   Product Name: ThermoTek Quickcare
   510(k) No.: K010502
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 5 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. Neil Devine
Responsible Third Party Official
Entela, Incorporated
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

Re: K041646
Trade/Device Name: ThermoTek™ Q5
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: July 19, 2004
Received: July 20, 2004

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K041646

Device Name: ThermoTek™ Q5

Indications for Use:

The **ThermoTek Q5** is intended for taking body temperature orally, rectally or under the arm.

Prescription Use _____ Or Over The Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subject C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Linda Hubbard for Anthony Watson
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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