510(k) Summary

K081162 (p.1of2)

**Submitter:**

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MAY - 8 2008

**Contact Person:** J. B. Allinson Jr.

**Date of Summary:** February 28, 2008

**Trade Name:** TempTouch® Dermal Thermometer

**Common Name:** Skin Surface Thermometer

**Device Description:** The TempTouch® is a handheld, 9V battery-operated device that measures the surface temperature of the skin. Operation is based on measuring the natural thermal infrared radiation emitted from the surface of the skin.

**Intended Use:** The TempTouch® is an infrared thermometer intended for the intermittent measurement and monitoring of human skin surface temperature in the home or clinic for use with people of all ages.

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

**Predicate Device(s):**
Omega Surface Temperature Scanner
(K873010)
Temp Touch Dermal Thermometer
(K050137)

**Technical Characteristics:** The TempTouch® Thermometer and the predicate devices are used to measure the temperature of a human by means of a thermopile infrared sensor transducer coupled with electronic signal amplification, conditioning, and a display unit.

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The Omega predicate employs solid- state electronic signal amplification, which is technology similar to the electronic surface mount technology used by the TempTouch® thermometer. Both display units employ solid-state displays, with the predicate using an LED display while the TempTouch thermometer uses an LCD display.

**Summary-Non-Clinical Performance Testing:**

| Performance Test | Results |
|---|---|
| Accuracy Test | Pass |
| Repeatability Tests | Pass |
| °F vs. °C tests | Pass |
| Variable Voltage Tests | Pass |
| Error Message Tests | Pass |
| Display Limits Tests | Pass |

**Conclusion:**

Since performance testing confirms conformance to the same standard as the predicate device, we conclude the device is substantially equivalent to that device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2008

Diabetica Solutions Incorporated
C/O Mr. Ned Devine
Responsible Third Party Official
Underwriters Laboratories, Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

Re: K081162
Trade/Device Name: TempTouch®
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: April 23, 2008
Received: April 24, 2008

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 (240) 276-0115. 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/industry/support/index.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

# STATEMENT OF INDICATIONS FOR USE

**510(k) Number if known:** K081162

**Device Name:** TempTouch®

**Indications for use:**

"The TempTouch® Dermal Thermometer is an infrared thermometer intended for the intermittent measurement of skin surface temperature of people of all ages."

**Prescription use:** XX **AND/OR** **Over-The-Counter use:** XX
**Part 21 CFR 801 Subpart D)** **(21 CFR 807 Subpart C)**

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

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

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

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