

FEB - 3 1997

510(k) SUMMARY OF SAFETY AND EFFICACY

DATE PREPARED: November 22, 1996

SUBMITTER: EntraCare, Inc.
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TRADE (PROPRIETARY)
NAME: EntraCare 1000 Thermometer

COMMON NAME: Thermometer

CLASSIFICATION NAME: Thermometer, Electronic, Clinical

DEVICE CLASSIFICATION: Class II

PREDICATE DEVICES:

1. Ivac Corp., Temp-Plus Vital Signs Measurement System, Model 2080 (K860436).
2. Diatek, Thermometer System, Model 600 (K833568).

DESCRIPTION OF DEVICE: The EntraCare Thermometer, Model 1000, is a hand-held, battery powered thermometer. This thermometer is capable of measuring and displaying temperatures over the entire human body temperature range (92.0° to 108.0° F or 33.0° to 42.0° C).

This device also is capable of calculating a persons approximate heart rate through the use of a stopwatch type function and will display the rate simultaneously with temperature. This feature acts like a stop watch and does not attempt to directly measure a patients pulse.

**STATEMENT OF
INTENDED USE:**

The EntraCare Thermometer, Model 1000, is intended to be used under a physicians orders when an accurate temperature measurement is required. The device is intended to be used orally or rectally in the human body temperature range of 92°F to 108°F. It may be used with infants, children, or adults in all settings under the order of a physician. The heart rate timer is also provided to aid in establishing a patients approximate heart rate.

**TECHNOLOGICAL
CHARACTERISTICS:**

The new device has the same technological characteristics (i.e., design, material, energy source) as the predicate devices. The specifications are illustrated in the substantial Equivalence Matrix on the following page.

SUBSTANTIAL EQUIVALENCE MATRIX

	Candidate EntraCare Model 1000	Predicate Ivac Corp. Model 2080	Predicate Diatek Model 600
FEATURES			
MONITOR MODE	YES	YES	YES
PREDICTIVE MODE	NO	YES	YES
NIGHT-VIEW DISPLAY	YES	YES	YES
°F / °C	YES	YES	YES
PULSE TIMER	YES	YES	YES
DISPOSABLE PROBE COVER	YES	YES	YES
BATTERY POWERED	YES	YES	YES
HAND HELD - PORTABLE	YES	YES	YES
REPLACEMENT PROBES	YES	YES	YES
DIAGNOSTIC SELF-TEST	YES	YES	YES