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510(k) SUMMARY - Lumiscope Model 2018 Thermometer

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Proprietary Name: Lumiscope Model 2018 Thermometer

Common/Usual Name: Digital Fever Thermometer with Quartz Clock
Oral and Axillary Thermometer

Classification Name: Clinical Electronic Thermometer (per 21 CFR 880.2910)

Legally Marketed Device: Hanson Scale Co. Clinical Electronic Thermometer - Model 7616-10

Device Description: The Lumiscope Model 2018 Thermometer is a thermometer of standard electrical transducer design, consisting of a flexible probe, connecting cord and display unit. The probe consists of a transducer and supporting plastic tube which houses the connection between the tube and cord. The display unit houses a 1.5V DC button battery, Liquid Crystal Display (LCD), slide switches for controlling the thermometer/clock mode and °F/°C mode, hour and minute set buttons, and temperature alert beeper.

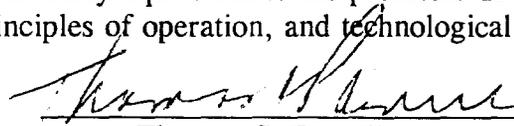
Intended Use: The Lumiscope Model 2018 Thermometer has the same intended use as the predicate device. It is indicated for use in the measurement of oral and axillary temperature. It is not intended for rectal (rectum) temperature measurement. The device also provides a clock function when not in the temperature mode. The Lumiscope Model 2018 Thermometer is intended for use by adults and may be used by the infant or pediatric patient population for measurements of axillary body temperature or for measurements of oral body temperature if the child is able to hold the thermometer beneath the tongue while his mouth is closed.

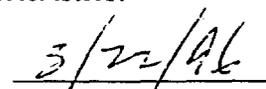
Technological Characteristics: The Lumiscope Model 2018 Thermometer has the same technological features as the predicate device: the mode of operation, physical specifications, operational, and biological specifications are identical.

Performance Data: The Lumiscope Model 2018 Thermometer meets the ASTM Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature (ASTM E 1112-86). Bench testing confirmed accuracy, precision and repeatability measurements specified in the labeling. For all body or fluid contacting materials, certification is made that the identical materials have been used in other legally marketed devices under the same use conditions.

Substantial Equivalence: The information provided demonstrates that the Lumiscope Model 2018 Thermometer is substantially equivalent to the predicate device since the devices have the same intended use, principles of operation, and technological characteristics.

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Date Prepared

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