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PT-Pac Portable Heating Pad

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510(k) SUMMARY:

The PT-Pac is a portable heating pad. It is a non-significant risk device similar to predicate devices (powered heating pads 890.5740) in providing sustained electrical powered heat to a defined body region. As with approved heating pads, the skin contacts only a biocompatible (100% cotton) cover. The PT-Pac claims the ability to provide soothing warmth in the temperature range of predicate devices. PT-Pac differs from alternating current powered devices in that it is powered by low-voltage, direct-current batteries, making it portable as well as safer than conventional heating pads. The PT-Pac uses highly reliable thermoelectric tiles to transfer heat. These are microprocessor-controlled, providing strict temperature regulation. The redundancy of two safety circuits, together with the finite time that the batteries can power the unit, make the safety of this device more robust than that of predicate devices.