

OCT 31 1996

Section 10 - Summary of Safety and Effectiveness *K961621*

Date of Preparation: October 29, 1996

Device Name: Therapy Concepts Water Circulating Treatment System

Classification Name: Pack, Hot or Cold Water, Circulating - 89 ILO

Manufacturer: Therapy Concepts, Inc. located at 11445 Moog Drive, St. Louis, MO 63146 (314)

Predicate Device: HOT/ICE Cold Therapy Cooler System, catalog number 42000, manufactured and marketed by InCare Medical Products, a division of Hollister Inc., 2000 Hollister Drive, Libertyville, IL 60048.

Device Description: The Therapy Concepts Water Circulating Treatment System will consist of five discreet modules. A reservoir module holding 1.5 liters of water. A low voltage DC pump with integral connection tubing. A wall mounted power supply to provide 7.5 volts DC to power the pump. A plastic/foam pad with connecting tubing, containing channels through which water is circulated and a form fitted sewn nylon carrying case.

Intended Use: The Therapy Concepts Water Circulating Treatment System will be used to pump chilled or room temperature water through a plastic pad that is placed on a mattress underneath the user and in so doing, will provide cold temperature therapy intended to temporarily assist in the localized reduction of minor swelling and pain. Pre-chilled water will be provided by adding ice cubes and water to the reservoir. The cooling rate is adjusted by adjusting the rate of flow of the water through the plastic pad.

Clinical and Non-Clinical Similarities and Differences: The Therapy Concepts, Inc. Water Circulating Treatment System and the InCare Medical Products, Inc. HOT/ICE Cold Therapy Cooler System are substantially equivalent since they both provide cold temperature therapy to temporarily assist in the localized reduction of minor swelling and pain.