

JAN 13 1997



K960511

Subject: 510(k) Summary of Safety and Effectiveness

Product: Gibeck, Inc. Warmbag Reusable Convective Warming Blanket

Summary:

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.

The Gibeck, Inc. Warmbag Reusable Convective Warming Blanket is a thermal regulation system as described in 21 CFR 870.5900. These products are substantially equivalent to the TropicAir Reusable Convective Warming Blankets distributed by Seabrook Medical, Inc.

The Gibeck, Inc. Warmbag Reusable Convective Blanket is similar in design, operation and function to the Seabrook Medical, Inc. TropicAir Reusable Convective Warming Blanket.

The principal differences between the Gibeck, Inc. Warmbag Reusable Convective Warming Blanket and the Seabrook Medical, Inc. TropicAir Reusable Convective Warming Blanket are the manufacturing processes, materials and labeling. These differences are not considered to be critical to the intended therapeutic, prosthetic or surgical use of the device nor should these differences significantly affect the safety or effectiveness of the device when used as labeled.

A handwritten signature in black ink, appearing to read 'B. D. Smith'.

Submitter/Contact Person

1/31/96

Date