

K953796

510(K) SUMMARY" AS REQUIRED BY 807.92(C)

Pursuant to 807.92(a)(1)

David Banks
3411 Oakcrest Drive
Shelby, NC 28150
704-487-1003

APR - 1 1996

Pursuant to 809.92(a)(2):

- Trade name - "Banks Hydro-Therapy Chair"
- Common name - Powered Sitz Bath
- Classification - Bath, Sitz, Powered, Class II device pursuant to 21 C.F.R. §890.5100

Pursuant to 809.92(a)(3) applicant claims substantial equivalence to legally marketed predicate device the Ferno-Washington, Inc. "Ferno-Ille-Hi-Lo, Jr.™". The predicate device is a mobile whirlpool bearing Registration No. K914125.

Pursuant to 809.92(a)(4), a description of the device is:

The Banks Hydro-Therapy Chair provides whirlpool therapy in the home so that patients do not require unnecessary hospitalization or require transportation to a hospital. The Banks Hydro-Chair comprises: a chair for supporting the patient, the chair may comprise a backrest, armrest, seat and frame; a hydro-pad, suction cups for removably fastening the chair to a bath tub, the lateral stability of the chair may be increased by a Stable Bar that is removably fastened to the backrest and a corresponding side wall of the bath in which the whirlpool therapy is taking place. The Hydro-pad is connected at the base of the Chair and the posterior opening of the Hydro-pad connects to a hose (typically rubberized tubing) which is connected to a blower motor which exerts a powerful pressure of air circulating through the ports of the Hydro-pad.

Streams of water jet through the ports causing a swirling motion of the water in which the Hydro-pad is immersed. The Chair is also

composed of a seat portion and the Chair is open so jets of water can reach the sacral, coccyx, rectum, groin and vaginal areas of the patient utilizing the Hydro-Therapy Chair. The seating and backing of the Chair are made of soft polyethylene material to prevent undue pressure to the skin during therapy. For handicapped and disabled persons, the arm frames of the Chair are easily removable. A more detailed description of the materials can be found in the drawings included in the "Attachments" section, section 2.

Pursuant to 809.92(a)(5), the intended use of the device is to aid in adding moisture to necrotic areas in order to aid in the debridement of wounds, to aid in the relief of pain and discomfort, to aid in the cleansing of open wounds, and as a form of physical therapy for certain types of pathologies.

Pursuant to 809.92(a)(6), basically, both the applicant's device("Banks Hydro-Therapy Chair") and the predicate device("Ferno-Washington, Inc.-Ile-Hi-Lo, Jr.™") agitate warm water to assist in the healing of patients requiring immersion in warm agitated water for such purposes as treatment of wounds, improvement of circulation, and relief of skin pain and discomfort.

Pursuant to 809.92(b)(1)-(3), applicant believes no assessment of performance data is necessary.

Pursuant to 809.92(d), applicant believes that no other information is necessary for 510(k) approval, but applicant will provide other information as reasonably required by the Food and Drug Administration.