

510(k) Summary of Safety and Effectiveness

ProBed Medical Technologies Inc.

Freedom Bed - Model PAR 3

APR - 1 1996

1. Submitter:

The 510(k) is submitted by ProBed Medical Technologies Inc., 44325 Yale Rd.W, Chilliwack, B.C., Canada V2R 4H2 Attn: Stephen B. Plummer. This 510(k) summary was prepared in September 1995.

2. Device name:

The 510(k) submission is for the ProBed Medical Technologies Inc., Freedom Bed™ Model PAR3.

3. Predicate device:

The device described in this submission is considered to be substantially equivalent to (list predicate). The predicate devices are legally marketed, having been found to be substantially equivalent through the 510(k) premarket notification process.

4. Device description:

The device is a programmable, automatically or manually operated repositioning bed designed for the prevention of decubitus ulcers. The device consists of 3 separate platen sections joined together with flexible hinges. The center section rotates left and right to a maximum of 30 degrees on each side, while the appropriate outer section rotates up to support and contain the sleeper. This provides a surface to transfer weight onto, as well as prevents the user from sliding or falling out of bed. The microprocessor based controller provides adjustment of time, angle and speed, as well as a choice of manual operation, automatic operation, or patient control. This allows most users to achieve independence from night time attendants and higher quality and duration of sleep. The bed has received UL 544, CSA, and FCC approvals.

5. Intended use:

The Freedom Bed PAR 3 is used to automatically reposition immobilized persons from side to side either manually or on a programmed schedule aide in the prevention of decubitus ulcers in bed ridden patients.

6. Comparison of technological characteristics:

We believe that the device has the same or similar technological features as compared to other devices currently manufactured or distributed in the United States. All 3 are electronically controlled and turn to a maximum of 30 degrees. The main difference is that while the predicate devices utilize air pressure to initiate the turning, the Freedom Bed uses 12 VDC powered actuators. Any variation in technology or difference of mechanism would not adversely affect the safety and effectiveness of the device.