JAN 22 1997 K964246

510(k) Summary

Nova Technologies, Inc.'s

Novabed Patient Transfer System

Submitter's Name, Address, and Telephone Number

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as Regulatory Counsel to Nova Technologies, Inc.

Date Prepared

October 11, 1996

Name of Device

Novabed Patient Transfer System

Classification Names

Powered Patient Transfer System, AC-Powered Hospital Bed, and Mechanical Wheelchair

Common Name

Patient Transfer System

Product Codes

FRZ, FNL, and IOR

Predicate Devices

Novabed Patient Transfer System

Intended Use

The intended use of Nova Technologies, Inc.'s Novabed System is to transfer a patient from or to the bed.

Substantial Equivalence

The cleared model of the Novabed System, which consists of a bed, a wheelchair, and a footrest attachment, is used to transfer a patient from or to a bed. The bed has a conveyor sheet which is pulled by rollers towards the foot of the bed during a patient transfer from the bed and towards the head of the bed during patient transfer to the bed. Each end of the conveyor sheet is connected to a motorized roller at each end of the bed. During transfer, the patient is moved to the end of the bed and, when partially on the pivoted wheelchair seat and legrest and partially on the bed, the patient is elevated to a vertical sitting position by the elevation of the bed against which the patient's back is resting. As the patient is elevated to a sitting position by the bed, the wheelchair automatically pivots until the seat is horizontal and the legrest vertical. The transfer is complete when the attendant disconnects the wheelchair from the bed and mounts the backrest to the wheelchair.

Nova is seeking clearance to modify the cleared Novabed System and market four models of the device with the modifications. Nova intends to make the

following modifications to the cleared Novabed System: (1) integrate the tilt table's footrest into the bed; (2) replace the discrete logic in the bed's electronic control unit with a microprocessor; (3) replace the motor used to automatically pivot the wheelchair ("the pivot motor") with a lever that an attendant can use to manually pivot the wheelchair; (4) replace the pivot motor and linkage mounted on the wheelchair with a motor and draw-bar mounted on the bed; (5) replace the wire cable driven by a linear actuator with a parallel linkage with a cantilever driven by a linear actuator to raise or lower the bed; (6) replace the wire cable that is used to create a data link between the bed and wheelchair with optical couplers; and (7) replace circuits in the sheet motor with reversible motor drive circuitry.

The modified models of the Novabed System have the same intended use as the cleared Novabed System: to transfer a patient to or from the bed. They also have equivalent principles of operation and technological characteristics as they use a conveyor sheet to pull the patient along the bed to a footrest that functions as a tilt table or wheelchair with a footrest that is attached to a bed and they pivot the wheelchair to align it with the bed for patient transfer. The minor technological differences between certain modified models of the device and the cleared Novabed System namely, the integration of the footrest, the attachment of the wheelchair pivot motor to the bed and the use of different linkage, the use of a parallel linkage with a cantilever, the use of an optical coupler, the use of a hand-held lever to pivot the wheelchair, and the use of reversible motor drive circuitry in the sheet motor, do not raise new questions of safety or effectiveness. In addition,

the software verification and validation demonstrate that the use of the microprocessor does not raise any new questions of safety or effectiveness. Thus, the modified models of the Novabed System are substantially equivalent to the cleared Novabed System.