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December 17, 2004

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

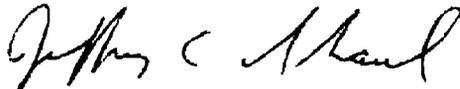
Re: Draft Guidance for Industry and Food and Drug Administration Staff: Hospital Bed System Dimensional Guidance to Reduce Entrapment [Docket No. 2004D-0343]

Ladies and Gentlemen:

Hill-Rom appreciates this opportunity to comment on the Draft Hospital Bed System Dimensional Guidance to Reduce Entrapment (Dimensional Guidance). As one of the original members of the Hospital Bed Safety Workgroup (HBSW), Hill-Rom has a long-standing commitment to the improvement of patient safety on hospital beds. Part of that commitment is our unwavering support of the establishment of the Dimensional Guidance.

That being said, Hill-Rom has concerns regarding the manner in which the Dimensional Guidance has been presented for public comment, particularly regarding the separation of the dimensions from the means to assess compliance to the Dimensional Guidance. Hill-Rom also has technical concerns regarding the Dimensional Guidance. These concerns are well expressed by both the Advanced Medical Technology Association (AdvaMed) and the Indiana Medical Device Manufacturers Council (IMDMC). Hill-Rom strongly supports their comments to this draft Dimensional Guidance.

Sincerely,



Jeffrey C. Shaul
Manager, Risk Assessment
Hill-Rom

2004D-0343

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