FDA 510(k) Premarket Notification

CLEARED

K103536 IBED WIRELESS WITH IBED AWARENESS

Dec 16, 2010
15 days to decision

K103536 · Product code: **FNL** · General Hospital
Source: https://www.510kdatabase.net/k103536/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bed, Ac-powered Adjustable Hospital (FNL)
Date received	Dec 1, 2010
Decision date	Dec 16, 2010
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Stryker Corporation**
Location	Malwah, NJ, US
Contact	Diane Horwitz
Website	http://www.stryker.com/
510(k) history	81 submissions · 81 cleared · 2010-2023

Stryker Corporation is an American multinational medical technology company headquartered in Portage, Michigan. The company develops and markets surgical equipment, neurotechnology, orthopedic implants, and patient safety systems used globally across medical specialties. Stryker has received FDA 510(k) clearances from total submissions between 2010 and 2023. The company's cleared devices span orthopedic surgery, neurosurgery, general and plastic surgery, and ear, nose, and throat specialties. This regulatory record reflects the company's broad portfolio across surgical an...