FDA 510(k) Premarket Notification

K060123 LEVELERT II FLUID LEVEL SENSOR

CLEARED

Feb 14, 2006
27 days to decision

K060123 · Product code: **FLN** · General Hospital
Source: https://www.510kdatabase.net/k060123/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Electric For Gravity Flow Infusion Systems (FLN)
Date received	Jan 18, 2006
Decision date	Feb 14, 2006
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Smith & Nephew, Inc.**
Location	Mchenry, IL, US
Contact	JANICE HASELTON
Website	http://www.smith-nephew.com/
510(k) history	530 submissions · 517 cleared · 1980-2026

Smith & Nephew, Inc. is a medical technology company focused on repair, regeneration, and replacement of soft and hard tissues. The company operates with a manufacturing facility in McHenry, US. Smith & Nephew has established a significant regulatory track record with the FDA. The company has received FDA 510(k) clearances from total submissions since 1980. Orthopedic devices represent the dominant category, accounting for 71% of submissions. The company remains active, with the latest clearance in 2025. Recent cleared devices reflect a strong focus on orthopedic surgical...