

K071175 OHMEDA MEDICAL GIRAFFE OMNIBED

Jul 17, 2007
81 days to decision

K071175 · Product code: **FMZ** · General Hospital
Source: <https://www.510kdatabase.net/k071175/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Incubator, Neonatal (FMZ)
Date received	Apr 27, 2007
Decision date	Jul 17, 2007
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ge Healthcare
Location	Waukesha, WI, US
Contact	AGATA SMIEJA
Website	http://www3.gehealthcare.com/en
510(k) history	168 submissions · 168 cleared · 2004-2026

GE HealthCare is an American multinational medical technology company headquartered in Waukesha, US. The company operates globally across medical imaging, ultrasound, patient care solutions, and pharmaceutical diagnostics. GE HealthCare has received FDA 510(k) clearances from total submissions since 2004. Radiology devices represent the dominant focus, accounting for 73% of regulatory submissions. The company's latest FDA 510(k) clearance was in 2026, reflecting continued innovation in medical imaging technologies. Recent cleared devices span Radiology specialties includi...