

K251663 Giraffe OmniBed Carestation (CS1)Oct 22, 2025
145 days to decisionK251663 · Product code: **FMZ** · General Hospital
Source: <https://www.510kdatabase.net/k251663/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Incubator, Neonatal (FMZ)
Date received	May 30, 2025
Decision date	Oct 22, 2025
Days to decision	145 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Giraffe Incubator Carestation (CS1)

APPLICANT

Company	Datex-Ohmeda, Inc.
Location	Madison, WI, US
Contact	Jordan Baum
510(k) history	60 submissions · 60 cleared · 1998-2025

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