

K260326 Giraffe™ OmniBed™ Carestation (CS1)

Jul 28, 2026
179 days to decision

K260326 · Product code: **FMZ** · General Hospital
Source: <https://www.510kdatabase.net/k260326/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Incubator, Neonatal (FMZ)
Date received	Jan 30, 2026
Decision date	Jul 28, 2026
Days to decision	179 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	Isabel McGann
510(k) history	61 submissions · 61 cleared · 1998-2026

510k Database - www.510kdatabase.net
Device record: <https://www.510kdatabase.net/k260326/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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