

K213551 Giraffe Omnibed Carestation CS1Mar 2, 2022
114 days to decisionK213551 · Product code: **FMT** · General Hospital
Source: <https://www.510kdatabase.net/k213551/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Warmer, Infant Radiant (FMT)
Date received	Nov 8, 2021
Decision date	Mar 2, 2022
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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