

**K213553 Giraffe Incubator Carestation CS1**Mar 2, 2022  
114 days to decisionK213553 · Product code: **FMZ** · General HospitalSource: <https://www.510kdatabase.net/k213553/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Incubator, Neonatal (FMZ)
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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213553/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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