

K152814 Giraffe OmniBed Carestation CS1Mar 17, 2016
171 days to decisionK152814 · Product code: **FMZ** · General Hospital
Source: <https://www.510kdatabase.net/k152814/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Incubator, Neonatal (FMZ)
Date received	Sep 28, 2015
Decision date	Mar 17, 2016
Days to decision	171 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ohmeda Medical, A Division of Datex-Ohmeda, Inc. A GE Company
Location	Laurel, MD, US
Contact	Kenny M Bello
510(k) history	1 submissions · 1 cleared · 2016-2016

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