

K152809 Giraffe Incubator Carestation CS1Dec 31, 2015
94 days to decisionK152809 · Product code: **FMZ** · General Hospital
Source: <https://www.510kdatabase.net/k152809/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Incubator, Neonatal (FMZ)
Date received	Sep 28, 2015
Decision date	Dec 31, 2015
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ohmeda Medical, A Division of Datex-Ohmeda, Inc.
Location	Laurel, MD, US
Contact	KENNY BELLO
510(k) history	3 submissions · 3 cleared · 2010-2015

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