

K132543 INFANT INCUBATORJul 3, 2014
324 days to decisionK132543 · Product code: **FMZ** · General Hospital
Source: <https://www.510kdatabase.net/k132543/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Incubator, Neonatal (FMZ)
Date received	Aug 13, 2013
Decision date	Jul 3, 2014
Days to decision	324 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bistos Co., Ltd.
Location	Flintville, TN, US
Contact	YOUNG CHI
510(k) history	11 submissions · 11 cleared · 2005-2025

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