

K172154 Isolette 8000 plusApr 19, 2018
276 days to decisionK172154 · Product code: **FMZ** · General Hospital
Source: <https://www.510kdatabase.net/k172154/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Incubator, Neonatal (FMZ)
Date received	Jul 17, 2017
Decision date	Apr 19, 2018
Days to decision	276 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Draeger Medical Systems, Inc.
Location	Andover, MA, US
Contact	Gale Winarsky
510(k) history	2 submissions · 2 cleared · 2015-2018

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