

K182977 Isolette 8000 PlusNov 21, 2018
26 days to decisionK182977 · Product code: **FMZ** · General Hospital
Source: <https://www.510kdatabase.net/k182977/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Incubator, Neonatal (FMZ)
Date received	Oct 26, 2018
Decision date	Nov 21, 2018
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Draeger Medical Systems, Inc.
Location	Danvers, MA, US
Contact	Karen Otrupchak
510(k) history	48 submissions · 48 cleared · 2003-2025

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