

K954204 DRAGER INCUBATOR 8000 ICApr 25, 1997
597 days to decisionK954204 · Product code: **FMZ** · General Hospital
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Incubator, Neonatal (FMZ)
Date received	Sep 6, 1995
Decision date	Apr 25, 1997
Days to decision	597 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Drager, Inc.
Location	Pittsburgh, PA, US
Contact	HARALD KNEUER
510(k) history	20 submissions · 15 cleared · 1991-1999

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