

K913394 INCUBATOR 8000 ICNov 22, 1991
115 days to decisionK913394 · Product code: **FMZ** · General Hospital
Source: <https://www.510kdatabase.net/k913394/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Incubator, Neonatal (FMZ)
Date received	Jul 30, 1991
Decision date	Nov 22, 1991
Days to decision	115 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Dragerwerk AG
Location	Mchenry, IL, US
Contact	STEFAN FREMBGEN
510(k) history	3 submissions · 3 cleared · 1980-1991

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