

K971198 BABYTHERM 8004 BABYTHERM 8010Oct 3, 1997
186 days to decisionK971198 · Product code: **FMT** · General Hospital
Source: <https://www.510kdatabase.net/k971198/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Warmer, Infant Radiant (FMT)
Date received	Mar 31, 1997
Decision date	Oct 3, 1997
Days to decision	186 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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