

**K963809 COOL-ZONE**Nov 20, 1996  
58 days to decisionK963809 · Product code: **FYA** · General Hospital  
Source: <https://www.510kdatabase.net/k963809/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Sep 23, 1996
Decision date	Nov 20, 1996
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Kappler USA</b>
Location	Guntersville, AL, US
Contact	PHILIP C MANN
510(k) history	2 submissions · 2 cleared · 1996-2000

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