

K820363 DISPOSABLE SURGICAL GARMENTSMar 8, 1982
27 days to decisionK820363 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k820363/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Feb 9, 1982
Decision date	Mar 8, 1982
Days to decision	27 days
Third-party review	No

APPLICANT

Company	Alphamedix, Inc.
Location	Mchenry, IL, US
510(k) history	7 submissions · 5 cleared · 1982-1985

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Device record: <https://www.510kdatabase.net/k820363/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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