

**K802885 L.A.F. ISOLATION PACK**Jan 15, 1981  
59 days to decisionK802885 · Product code: **FYA** · General Hospital  
Source: <https://www.510kdatabase.net/k802885/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Nov 17, 1980
Decision date	Jan 15, 1981
Days to decision	59 days
Third-party review	No

**APPLICANT**

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Company	<b>Action Medical Systems, Inc.</b>
Location	Mchenry, IL, US
510(k) history	2 submissions · 2 cleared · 1981-1983

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Device record: <https://www.510kdatabase.net/k802885/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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