

**K954674 P1OP2B OR P1O92T**Jan 30, 1997  
478 days to decisionK954674 · Product code: **FYA** · General Hospital  
Source: <https://www.510kdatabase.net/k954674/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Oct 10, 1995
Decision date	Jan 30, 1997
Days to decision	478 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Kay Borch A/S</b>
Location	Houston, TX, US
Contact	MICHAEL MOSEGAARD
510(k) history	1 submissions · 1 cleared · 1997-1997

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