

**K801069 STERILE ISOLATION GOWN**May 20, 1980  
14 days to decisionK801069 · Product code: **FYC** · General Hospital  
Source: <https://www.510kdatabase.net/k801069/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	May 6, 1980
Decision date	May 20, 1980
Days to decision	14 days
Third-party review	No

**APPLICANT**

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Company	<b>Medspec Corp.</b>
Location	Mchenry, IL, US
510(k) history	15 submissions · 15 cleared · 1980-1981

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Device record: <https://www.510kdatabase.net/k801069/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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