

K803158 IRRADIATED BOUNDARY DEVICESJan 15, 1981
55 days to decisionK803158 · Product code: **FYA** · General HospitalSource: <https://www.510kdatabase.net/k803158/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Nov 21, 1980
Decision date	Jan 15, 1981
Days to decision	55 days
Third-party review	No

APPLICANT

Company	The Buckeye Cellulose Corp.
Location	Mchenry, IL, US
510(k) history	18 submissions · 18 cleared · 1980-1983

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Device record: <https://www.510kdatabase.net/k803158/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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