FDA 510(k) Premarket Notification

K882470 STERILE DISPOSABLE SURGICAL GOWNS

CLEARED

Aug 3, 1988
49 days to decision

K882470 · Product code: **FYA** · General Hospital
Source: https://www.510kdatabase.net/k882470/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Jun 15, 1988
Decision date	Aug 3, 1988
Days to decision	49 days
Third-party review	No

APPLICANT

Company	**Bolden Products, Div. of the Transport Group**
Location	Miami, FL, US
Contact	ALEXANDER LUCIO
510(k) history	1 submissions · 1 cleared · 1988-1988

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k882470/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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