

K834332 BOUNDARY SINGLE-USE GOWNSMay 1, 1984
141 days to decisionK834332 · Product code: FYA · General Hospital
Source: <https://www.510kdatabase.net/k834332/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Dec 12, 1983
Decision date	May 1, 1984
Days to decision	141 days
Third-party review	No

APPLICANT

Company	Procter & Gamble Mfg. Co.
Location	Mchenry, IL, US
Website	https://www.pg.com
510(k) history	72 submissions · 72 cleared · 1976-1988

Procter & Gamble Mfg. Co. is a consumer health and personal care manufacturer headquartered in McHenry, US. The company has a long history of developing products across multiple healthcare categories. The company received FDA 510(k) clearances from total submissions, with no denied submissions on record. Regulatory activity spans from 1976 to 1988, establishing a historical record primarily in Obstetrics & Gynecology and Gastroenterology & Urology device categories. The company is inactive in the FDA 510(k) clearance database, with no submissions recorded in the past seven...

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