FDA 510(k) Premarket Notification

K834339 BOUNDARY REINFORCED SINGLE-USE GOWNS

CLEARED

Mar 5, 1984
84 days to decision

K834339 · General & Plastic Surgery
Source: https://www.510kdatabase.net/k834339/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Dec 12, 1983
Decision date	Mar 5, 1984
Days to decision	84 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 seve...