

K791062 BOUNDARY SPECIALTY GOWNJun 20, 1979
12 days to decisionK791062 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k791062/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Gown, Surgical (FYA) |
| Date received | Jun 8, 1979 |
| Decision date | Jun 20, 1979 |
| Days to decision | 12 days |
| Third-party review | No |

APPLICANT

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|----------------|---|
| 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...