

**K842958 BOUNDARY SINGLE-USE OR GOWN**Aug 17, 1984  
21 days to decisionK842958 · Product code: FYA · General Hospital  
Source: <https://www.510kdatabase.net/k842958/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Jul 27, 1984
Decision date	Aug 17, 1984
Days to decision	21 days
Third-party review	No

**APPLICANT**

---

Company	<b>Procter &amp; Gamble Mfg. Co.</b>
Location	Mchenry, IL, US
Website	<a href="https://www.pg.com">https://www.pg.com</a>
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...

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k842958/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026