

**K802148 BOUNDARY SINGLE-USE DRAPE**Sep 26, 1980  
18 days to decisionK802148 · Product code: **KKX** · General Hospital  
Source: <https://www.510kdatabase.net/k802148/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drape, Surgical (KKX)
Date received	Sep 8, 1980
Decision date	Sep 26, 1980
Days to decision	18 days
Third-party review	No

**APPLICANT**

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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...

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