

**K011996 TAMPAX PEARL SCENTED AND UNSCENTED  
TAMPONS - JUNIOR, REGULAR, SUPER & SUPER PLUS**Sep 19, 2001  
84 days to decisionK011996 · Product code: **HIL** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k011996/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                   |
| Submission type       | Traditional  |
| Device classification | Tampon, Menstrual, Scented, Scented-deodorized (HIL) |
| Date received         | Jun 27, 2001   |
| Decision date         | Sep 19, 2001   |
| Days to decision      | 84 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Procter &amp; Gamble Co.</b>                     |
| Location       | Cincinnati, OH, US                                  |
| Contact        | MARK M ANDERSON                                     |
| Website        | <a href="http://www.pg.com/">http://www.pg.com/</a> |
| 510(k) history | 23 submissions · 23 cleared · 1988-2014             |

Procter & Gamble Co. is a consumer health and personal care company headquartered in Cincinnati, US. The company develops and markets a broad range of health and wellness products globally. Procter & Gamble has received FDA 510(k) clearances from total submissions, with no denied submissions on record. The company's regulatory focus has centered on Obstetrics & Gynecology devices, which represent the dominant category of its submissions. FDA 510(k) clearances span from 1988 to 2014, establishing a historical regulatory record in feminine care and oral health device categories.

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011996/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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 June 6, 2026