

K131543 TAMPAX(R) L PLASTIC TAMPONS, UNSCENTEDJun 20, 2013
22 days to decisionK131543 · Product code: **HEB** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k131543/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Tampon, Menstrual, Unscented (HEB)
Date received	May 29, 2013
Decision date	Jun 20, 2013
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Procter & Gamble Co.
Location	Cincinnati, OH, US
Contact	KATHLEEN BLIESZNER
Website	http://www.pg.com/
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.