FDA 510(k) Premarket Notification

K003843 ENVIVE MINIFORMS

CLEARED

Feb 8, 2001
58 days to decision

K003843 · Product code: **HHD** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k003843/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pad, Menstrual, Unscented (HHD)
Date received	Dec 12, 2000
Decision date	Feb 8, 2001
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Procter & Gamble Co.**
Location	Cincinnati, OH, US
Contact	KATHLEEN C BLIEZNER
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 catego...