FDA 510(k) Premarket Notification

K010365 ORTHO CONTROL FEMALE URINARY CONTROL DEVICE

CLEARED

Apr 30, 2001
82 days to decision

K010365 · Product code: **MNG** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k010365/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	External Urethral Occluder, Urinary Incontinence-control, Female (MNG)
Date received	Feb 7, 2001
Decision date	Apr 30, 2001
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Personal Products Co.**
Location	Mchenry, IL, US
Contact	MARYLOU PANICO
510(k) history	45 submissions · 45 cleared · 1976-2007