

K963858 FEMASSIST URINARY DEVICEOct 21, 1997
391 days to decisionK963858 · Product code: **MNG** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k963858/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	External Urethral Occluder, Urinary Incontinence-control, Female (MNG)
Date received	Sep 25, 1996
Decision date	Oct 21, 1997
Days to decision	391 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Insight Medical Corp.
Location	Toronto, Ontario, CA
Contact	ROBERT W SCHAEFER
510(k) history	3 submissions · 3 cleared · 1994-1998

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