

K974645 FEMASSIST FLEXIBLEFeb 12, 1998
62 days to decisionK974645 · Product code: **MNG** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k974645/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	External Urethral Occluder, Urinary Incontinence-control, Female (MNG)
Date received	Dec 12, 1997
Decision date	Feb 12, 1998
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Insight Medical Corp.
Location	Toronto, Ontario, CA
Contact	MICHAEL G VERGANO
510(k) history	3 submissions · 3 cleared · 1994-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k974645/> Data sourced from FDA 510(k) public records (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. - Generated July 1, 2026