

K954215 MINIGUARDMay 8, 1996
243 days to decisionK954215 · Product code: **MNG** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k954215/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	External Urethral Occluder, Urinary Incontinence-control, Female (MNG)
Date received	Sep 8, 1995
Decision date	May 8, 1996
Days to decision	243 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Advanced Surgical Intervention, Inc.
Location	San Clemente, CA, US
Contact	ROBERT F ROSENBLUTH
510(k) history	9 submissions · 9 cleared · 1988-1996

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