

**K971359 RESTORE (A.K.A. CAPSURE)**Nov 14, 1997  
217 days to decisionK971359 · Product code: **MNG** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k971359/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	External Urethral Occluder, Urinary Incontinence-control, Female (MNG)
Date received	Apr 11, 1997
Decision date	Nov 14, 1997
Days to decision	217 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nebi, Inc.</b>
Location	Worcester, MA, US
Contact	JEFFREY A DANN
510(k) history	3 submissions · 3 cleared · 1995-1999

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