

K974173 ERECAID SYSTEM/STAY EREC SYSTEMFeb 25, 1998
112 days to decisionK974173 · Product code: **LKY** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k974173/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, External Penile Rigidity (LKY)
Date received	Nov 5, 1997
Decision date	Feb 25, 1998
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Imagyn Medical Technologies, Inc.
Location	Richland, MI, US
Contact	RONALD H BERGESON
510(k) history	7 submissions · 6 cleared · 1998-2003

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