

K141958 ERB ENDORECTAL BALLOONNov 18, 2014
123 days to decisionK141958 · Product code: **PCT** · Radiology
Source: <https://www.510kdatabase.net/k141958/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prostate Immobilizer Rectal Balloon (PCT)
Date received	Jul 18, 2014
Decision date	Nov 18, 2014
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Edge Medical, LLC
Location	Lutsen, MN, US
Contact	GREGORY MATHISON
510(k) history	1 submissions · 1 cleared · 2014-2014

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