

K141252 GUARDIAN URETHRAL SHEATHJun 9, 2014
26 days to decisionK141252 · Product code: **KNY** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k141252/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Accessories, Catheter, G-u (KNY)
Date received	May 14, 2014
Decision date	Jun 9, 2014
Days to decision	26 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Solace Therapeutics
Location	Farmingham, MA, US
Contact	ADAM HEROUX
510(k) history	3 submissions · 3 cleared · 2013-2017

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