

K131803 GUARDIAN URETHRAL SHEATHAug 20, 2013
62 days to decisionK131803 · Product code: **KNY** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k131803/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Accessories, Catheter, G-u (KNY)
Date received	Jun 19, 2013
Decision date	Aug 20, 2013
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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