

K140441 BI-FLEX URETERAL ACCESS SHEATHJun 17, 2014
116 days to decisionK140441 · Product code: **KNY** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k140441/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Catheter, G-u (KNY)
Date received	Feb 21, 2014
Decision date	Jun 17, 2014
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Promepla Sam
Location	Monaco, MC
Contact	MOHAMED REKIK
510(k) history	5 submissions · 5 cleared · 2012-2018

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