

K182144 Bi-Flex EvoSep 7, 2018
30 days to decisionK182144 · Product code: **KNY** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k182144/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Accessories, Catheter, G-u (KNY)
Date received	Aug 8, 2018
Decision date	Sep 7, 2018
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182144/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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