

**K192183 RocaTub Ureteral Catheter**Apr 23, 2020  
255 days to decisionK192183 · Product code: **EYB** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k192183/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Ureteral, Gastro-urology (EYB)
Date received	Aug 12, 2019
Decision date	Apr 23, 2020
Days to decision	255 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Promepal Sam</b>
Location	Monaco, MC
Contact	Mohamed Rekik
510(k) history	1 submissions · 1 cleared · 2020-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192183/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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