

K181673 Rigi10 Malleable Penile ProsthesisApr 15, 2019
294 days to decisionK181673 · Product code: **FAE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k181673/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Prosthesis, Penile (FAE)
Date received	Jun 25, 2018
Decision date	Apr 15, 2019
Days to decision	294 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Rigicon, Inc.
Location	Hauppauge, NY, US
Contact	Ahmet Melih Luleci
510(k) history	1 submissions · 1 cleared · 2019-2019

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