

K182511 SimplCathMar 20, 2019
189 days to decisionK182511 · Product code: **GBM** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k182511/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urethral (GBM)
Date received	Sep 12, 2018
Decision date	Mar 20, 2019
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	F&S Medical Solutions, LLC
Location	Omaha, NE, US
Contact	Sonia M. Rocha-Sanchez
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Vision28
Contact	Tom Renner

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182511/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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