FDA 510(k) Premarket Notification

K182511 SimplCath

CLEARED

Mar 20, 2019
189 days to decision

K182511 · 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