FDA 510(k) Premarket Notification

K181669 ConvertX Biliary Stent System

CLEARED

Mar 14, 2019
262 days to decision

K181669 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k181669/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jun 25, 2018
Decision date	Mar 14, 2019
Days to decision	262 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Brightwater Medical**
Location	Dunlap, IL, US
Contact	Bob Smouse
510(k) history	2 submissions · 2 cleared · 2016-2019