

K181669 ConvertX Biliary Stent SystemMar 14, 2019
262 days to decisionK181669 · Product code: **FGE** · Gastroenterology & UrologySource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181669/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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