FDA 510(k) Premarket Notification

K063481 MODIFICATION TO RX HERCULINK ELITE BILIARY STENT SYSTEM

CLEARED

Sep 14, 2007
301 days to decision

K063481 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k063481/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Nov 17, 2006
Decision date	Sep 14, 2007
Days to decision	301 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Abbott Vascular, Inc.**
Location	Redwood, CA, US
Contact	NADINE SMITH
510(k) history	20 submissions · 17 cleared · 2000-2014