FDA 510(k) Premarket Notification

K111766 SUPERA VERITAS INTERWOVEN SELF-EXPANDING NITINOL STENT TRANSHEPTIC BILIARY SYSTEMS

CLEARED

Oct 19, 2011
118 days to decision

K111766 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k111766/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jun 23, 2011
Decision date	Oct 19, 2011
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Idev Technologies, Inc.**
Location	Houston, TX, US
Contact	DARENE GARNER
510(k) history	11 submissions · 4 cleared · 2003-2013