FDA 510(k) Premarket Notification

K093893 SUPERA VERITAS INTERWOVEN SELF-EXPANDING NITINOL STENT TRANSHEPATIC BILIARY SYSTEM

CLEARED

Oct 5, 2010
291 days to decision

K093893 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k093893/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Dec 18, 2009
Decision date	Oct 5, 2010
Days to decision	291 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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