FDA 510(k) Premarket Notification

CLEARED

K022026 MEDTRONIC AVE BRIDGE POLARIS BILIARY STENT SYSTEM (POLARIS)

Jul 19, 2002
28 days to decision

K022026 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k022026/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jun 21, 2002
Decision date	Jul 19, 2002
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Ave, Inc.**
Location	Santa Rosa, CA, US
Contact	KEVIN DRISKO
510(k) history	13 submissions · 2 cleared · 1999-2003