FDA 510(k) Premarket Notification

K014205 MODIFICATION TO BRIDGE SELF-EXPANDING BILIARY STENT DELIVERY SYSTEM (BRIDGE SE)

CLEARED

Jan 14, 2002
24 days to decision

K014205 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k014205/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Dec 21, 2001
Decision date	Jan 14, 2002
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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