FDA 510(k) Premarket Notification

K041796 PRECISE RX NITINOL STENT TRANSHEPATIC BILIARY SYSTEM

CLEARED

Aug 3, 2004
32 days to decision

K041796 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k041796/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jul 2, 2004
Decision date	Aug 3, 2004
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cordis Corporation**
Location	Warren, NJ, US
Contact	ELENA S JUGO
510(k) history	13 submissions · 12 cleared · 2004-2022