FDA 510(k) Premarket Notification

CLEARED

K042204 MODIFICATION TO PROTEGE GPS SELF-EXPANDING NITINOL STENT

Aug 23, 2004
7 days to decision

K042204 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k042204/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Aug 16, 2004
Decision date	Aug 23, 2004
Days to decision	7 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ev3, Inc.**
Location	Plymouth, MN, US
Contact	GLEN D SMYTHE
510(k) history	35 submissions · 26 cleared · 2003-2014