FDA 510(k) Premarket Notification

K032206 PARAMOUNT MINI STENT AND DELIVERY SYSTEM BILIARY INDICATION

CLEARED

Aug 8, 2003
21 days to decision

K032206 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k032206/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jul 18, 2003
Decision date	Aug 8, 2003
Days to decision	21 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