FDA 510(k) Premarket Notification

K010714 EXPANDER, MODELS 1400880, 1401280, 1401680, 1401880, 1410420, 1410620, 1410830

CLEARED

Jan 21, 2003
683 days to decision

K010714 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k010714/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Mar 9, 2001
Decision date	Jan 21, 2003
Days to decision	683 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medi-Globe Corp.**
Location	Irvine, CA, US
Contact	GERHARDT SEIWERTH
510(k) history	18 submissions · 17 cleared · 1990-2006