FDA 510(k) Premarket Notification

K033212 LIFESTENT SDS BILIARY ENDOPROSTHESIS

CLEARED

Oct 30, 2003
27 days to decision

K033212 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k033212/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Oct 3, 2003
Decision date	Oct 30, 2003
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Orbus Medical Technologies**
Location	Fort Lauderdale, FL, US
Contact	JIM CLOSSICK
510(k) history	8 submissions · 0 cleared · 2001-2004