FDA 510(k) Premarket Notification

K023308 LIFESTENT SDS BILIARY ENDOPROSTHESIS, LIFESTENT XL SDS BILIARY ENDOPROSTHESIS

CLEARED

Apr 14, 2003
193 days to decision

K023308 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k023308/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Oct 3, 2002
Decision date	Apr 14, 2003
Days to decision	193 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