FDA 510(k) Premarket Notification

CLEARED

K033333 SINGLE USE 3-LUMEN BALLOON CATHETER, MODELS B-230Q-A AND B-230Q-B

Nov 14, 2003
29 days to decision

K033333 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k033333/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Oct 16, 2003
Decision date	Nov 14, 2003
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Aomori Olympus Co., Ltd.**
Location	Melville, NY, US
Contact	TINA STEFFANIE-OAK
510(k) history	7 submissions · 7 cleared · 2003-2005