FDA 510(k) Premarket Notification

K024033 XTJF-160AF DUODENOVIDEOSCOPE

CLEARED

Dec 20, 2002
14 days to decision

K024033 · Product code: **FDT** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k024033/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Duodenoscope And Accessories, Flexible/rigid (FDT)
Date received	Dec 6, 2002
Decision date	Dec 20, 2002
Days to decision	14 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Olympus Optical Co., Ltd.**
Location	Melville, NY, US
Contact	LAURA STORMS-TYLER
Website	http://www.olympus-global.com/
510(k) history	22 submissions · 22 cleared · 2000-2003

Olympus Optical Co., Ltd. is a global medical device manufacturer headquartered in Melville, US. The company specializes in endoscopic and surgical imaging technologies for minimally invasive procedures. Olympus received FDA 510(k) clearances from total submissions between 2000 and 2003. The company's cleared devices span multiple surgical specialties, with particular strength in endoscopic visualization systems for gastroenterology, urology, otolaryngology, and general surgery. Notable cleared products include bronchofiberscopes, gastrovideoscopes, cystofiberscopes, and ...