FDA 510(k) Premarket Notification

CLEARED

K032092 OLYMPUS XCYF-TP3 CYSTOFIBERSCOPE/NEPHROFIBERSCOPE

Jul 16, 2003
9 days to decision

K032092 · Product code: **FCL** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k032092/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Forceps, Biopsy, Non-electric (FCL)
Date received	Jul 7, 2003
Decision date	Jul 16, 2003
Days to decision	9 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Olympus Optical Co., Ltd.**
Location	Melville, NY, US
Contact	MASAO WADA
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 ...