FDA 510(k) Premarket Notification

K871517 OLYMPUS PF-25 ULTRATHIN ANGIOSCOPE

CLEARED

Nov 30, 1987
224 days to decision

K871517 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k871517/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Apr 20, 1987
Decision date	Nov 30, 1987
Days to decision	224 days
Third-party review	No

APPLICANT

Company	**Olympus Corp.**
Location	Mchenry, IL, US
Contact	WAYNE LIPSON
Website	https://www.olympus-global.com
510(k) history	142 submissions · 140 cleared · 1978-1995

Olympus Corp. is a Japanese optics and imaging manufacturer founded in 1919. The company operates from McHenry, US, and holds approximately 70 percent of the global endoscope market. Olympus has received FDA 510(k) clearances from total submissions between 1978 and 1995. The company's cleared devices span gastroenterology, urology, obstetrics, gynecology, and chemistry specialties. This regulatory record reflects the company's historical focus on endoscopic surgical instruments and related technologies. Notable cleared device categories include resection electrodes, fiber...