FDA 510(k) Premarket Notification

K873100 OLYMPUS ANGIOSCOPY SHEATH

CLEARED

Feb 29, 1988
206 days to decision

K873100 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k873100/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Aug 7, 1987
Decision date	Feb 29, 1988
Days to decision	206 days
Third-party review	No

APPLICANT

Company	**Olympus Corp.**
Location	Mchenry, IL, US
Contact	WAYNE E 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...