

K884310 ANGIOPUMP TUBING SETJan 10, 1989
89 days to decisionK884310 · Product code: **DWF** · Cardiovascular
Source: <https://www.510kdatabase.net/k884310/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Oct 13, 1988
Decision date	Jan 10, 1989
Days to decision	89 days
Third-party review	No

APPLICANT

Company	Olympus Corp.
Location	Mchenry, IL, US
Contact	YUTAKA OTANI
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...
