FDA 510(k) Premarket Notification

K930241 OLYMPUS DISPOSABLE BIOPSY FORCEPS

CLEARED

Apr 20, 1993
91 days to decision

K930241 · Product code: **KNW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k930241/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Jan 19, 1993
Decision date	Apr 20, 1993
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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