FDA 510(k) Premarket Notification

CLEARED

K931835 OLYMPUS REPLY INORGANIC PHOSPHOROUS REAGENT

Sep 8, 1993
148 days to decision

K931835 · Product code: **CEO** · Chemistry
Source: https://www.510kdatabase.net/k931835/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Phosphomolybdate (colorimetric), Inorganic Phosphorus (CEO)
Date received	Apr 13, 1993
Decision date	Sep 8, 1993
Days to decision	148 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Olympus Corp.**
Location	Mchenry, IL, US
Contact	LAURA STORMS-TYLER
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...