FDA 510(k) Premarket Notification

K923982 OLYMPUS OES LAPAROSCOPY SYSTEM

CLEARED

Mar 15, 1993
220 days to decision

K923982 · Product code: **GCJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k923982/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Aug 7, 1992
Decision date	Mar 15, 1993
Days to decision	220 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Olympus Corp.**
Location	Mchenry, IL, US
Contact	ANDREW FLEISCHACKER
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...