FDA 510(k) Premarket Notification

K911904 MODELS UES-10 & PSD-10

CLEARED

Jul 26, 1991
88 days to decision

K911904 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k911904/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 29, 1991
Decision date	Jul 26, 1991
Days to decision	88 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Olympus Corp.**
Location	Mchenry, IL, US
Contact	DANIEL J.DILLION
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...