

K021852 OLYMPUS PSD-20 ELECTROSURGICAL SYSTEM & ITS ASSOCIATED ACCESSORIESFeb 11, 2003
251 days to decisionK021852 · Product code: **GEI** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k021852/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jun 5, 2002
Decision date	Feb 11, 2003
Days to decision	251 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Olympus Optical Co., Ltd.
Location	Melville, NY, US
Contact	LAURA STORMS-TYLER
Website	http://www.olympus-global.com/
510(k) history	22 submissions · 22 cleared · 2000-2003

Olympus Optical Co., Ltd. is a global medical device manufacturer headquartered in Melville, US. The company specializes in endoscopic and surgical imaging technologies for minimally invasive procedures. Olympus received FDA 510(k) clearances from total submissions between 2000 and 2003. The company's cleared devices span multiple surgical specialties, with particular strength in endoscopic visualization systems for gastroenterology, urology, otolaryngology, and general surgery. Notable cleared products include bronchofiberscopes, gastrovideoscopes, cystofiberscopes, and ...