K023280 OLYMPUS PSD-20 ELECTROSURGICAL SYSTEM AND ITS ASSOCIATED ACCESSORIES

CLEARED

Dec 19, 2002
79 days to decision

K023280 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k023280/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Oct 1, 2002
Decision date	Dec 19, 2002
Days to decision	79 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 ...