

K021204 OLYMPUS BF TYPE UM40May 1, 2002
15 days to decisionK021204 · Product code: **PSV** · Radiology
Source: <https://www.510kdatabase.net/k021204/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ultrasound Bronchoscope (PSV)
Date received	Apr 16, 2002
Decision date	May 1, 2002
Days to decision	15 days
Third-party review	Yes
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 ...
