

K961048 OLYMPUS MH-246R BALLOON SHEATHSep 16, 1996
185 days to decisionK961048 · Product code: **ODG** · Radiology
Source: <https://www.510kdatabase.net/k961048/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Ultrasound System, Gastroenterology-urology (ODG)
Date received	Mar 15, 1996
Decision date	Sep 16, 1996
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Olympus America, Inc.
Location	Lake Success, NY, US
Contact	BARRY E SANDS
510(k) history	149 submissions · 149 cleared · 1994-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k961048/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 18, 2026