

K982734 OLYMPUS MH-246R BALLOON SHEATH, FOR URINARY TRACT USE

Oct 5, 1998
61 days to decision

K982734 · Product code: **ODG** · Radiology
Source: <https://www.510kdatabase.net/k982734/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Ultrasound System, Gastroenterology-urology (ODG)
Date received	Aug 5, 1998
Decision date	Oct 5, 1998
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	The Olympus Optical Co.
Location	Melville, NY, US
Contact	LAURA STORMS-TAYLOR
510(k) history	22 submissions · 22 cleared · 1998-2003

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Device record: <https://www.510kdatabase.net/k982734/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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