

**K982725 OLYMPUS MH-246R BALLOON SHEATH, FOR FEMALE REPRODUCTIVE TRACT USE**Oct 23, 1998  
79 days to decisionK982725 · Product code: ITX · Radiology  
Source: <https://www.510kdatabase.net/k982725/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Aug 5, 1998
Decision date	Oct 23, 1998
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Olympus America, Inc.</b>
Location	Lake Success, NY, US
Contact	LAURA STORMS-TAYLOR
510(k) history	149 submissions · 149 cleared · 1994-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k982725/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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