

**K011886 OLYMPUS EU-M60 EUS EXERA ENDOSCOPIC  
ULTRASOUND CTR, EUS EXERA ULTRASONIC  
GASTROVIDEOSCOPE OLYMPUS GF TYPE UM 160,**Aug 27, 2001  
73 days to decisionK011886 · Product code: **ODG** · Radiology  
Source: <https://www.510kdatabase.net/k011886/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Ultrasound System, Gastroenterology-urology (ODG)
Date received	Jun 15, 2001
Decision date	Aug 27, 2001
Days to decision	73 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-TYLER
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/k011886/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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