

K100345 SYSTEMS INTEGRATION MODEL: ENDOALPHAMar 22, 2010
45 days to decisionK100345 · Product code: **ODA** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k100345/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Central Control Unit (ODA)
Date received	Feb 5, 2010
Decision date	Mar 22, 2010
Days to decision	45 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Olympus Medical Systems Corporation
Location	Melville, NY, US
Contact	STACY KLUESNER
510(k) history	81 submissions · 81 cleared · 2004-2026

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