FDA 510(k) Premarket Notification

CLEARED

K071254 SMALL INTESTINAL VIDEOSCOPE SYSTEM

Mar 25, 2008
326 days to decision

K071254 · Product code: **FDA** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k071254/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enteroscope And Accessories (FDA)
Date received	May 4, 2007
Decision date	Mar 25, 2008
Days to decision	326 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Olympus Medical Systems Corporation**
Location	Melville, NY, US
Contact	LAURA STORMS-TYLER
510(k) history	81 submissions · 81 cleared · 2004-2026

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k071254/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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