

**K964661 HX-20/21-1 ENDOSCOPIC LIGATOR**Oct 30, 1997  
344 days to decisionK964661 · Product code: **MND** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k964661/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ligator, Esophageal (MND)
Date received	Nov 20, 1996
Decision date	Oct 30, 1997
Days to decision	344 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	SUBHASH PATEL
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/k964661/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 18, 2026