

K190164 CleverLock Guidewire Locking Device and Biopsy CapApr 4, 2019
63 days to decisionK190164 · Product code: **ODC** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k190164/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope Channel Accessory (ODC)
Date received	Jan 31, 2019
Decision date	Apr 4, 2019
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Olympus Surgical Technologies America
Location	Southborough, MA, US
Contact	Mary Anne Patella
510(k) history	12 submissions · 12 cleared · 2012-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190164/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026