

K160117 AbClose - Port Site Closure DeviceSep 9, 2016
234 days to decisionK160117 · Product code: **OCW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k160117/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Tissue Approximation Device (OCW)
Date received	Jan 19, 2016
Decision date	Sep 9, 2016
Days to decision	234 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medeon Biodesign, Inc.
Location	Taipei, TW
Contact	GRETA CHANG
510(k) history	7 submissions · 7 cleared · 2015-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160117/> 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 June 28, 2026