

K193652 AbClose - Port Site Closure DeviceMar 26, 2020
87 days to decisionK193652 · Product code: **OCW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k193652/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Tissue Approximation Device (OCW)
Date received	Dec 30, 2019
Decision date	Mar 26, 2020
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193652/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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