

K192891 Laparoscope Lens Shield Device (LENS)Nov 7, 2019
28 days to decisionK192891 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k192891/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Oct 10, 2019
Decision date	Nov 7, 2019
Days to decision	28 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/k192891/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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