

K151117 Laparoscope Lens Shield DeviceAug 20, 2015
115 days to decisionK151117 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k151117/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Apr 27, 2015
Decision date	Aug 20, 2015
Days to decision	115 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/k151117/> 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