

K181791 SIMPLYSTRONG, SIMPLYEZEEAug 21, 2018
47 days to decisionK181791 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k181791/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Jul 5, 2018
Decision date	Aug 21, 2018
Days to decision	47 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Genicon, Inc.
Location	Winter Park, FL, US
Contact	Katlyn Kachman
510(k) history	6 submissions · 6 cleared · 2016-2019

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