

**K163654 VersaOne fascial closure system bladed trocar,
VersaOne fascial closure system bladeless trocar, VersaOne
fascial closure system optical trocar**

Mar 8, 2017
75 days to decision

K163654 · Product code: **GCJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k163654/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Dec 23, 2016
Decision date	Mar 8, 2017
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Covidien, LLC
Location	Mansfield, MA, US
Contact	Gary LeMere
510(k) history	88 submissions · 85 cleared · 2010-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k163654/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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