

**K210495 Port Access System**Jun 18, 2021  
116 days to decisionK210495 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k210495/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Feb 22, 2021
Decision date	Jun 18, 2021
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Surgical Innovations Limited</b>
Location	Leeds, GB
Contact	Stephen Seed
510(k) history	2 submissions · 2 cleared · 2019-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210495/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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