

K191177 LENS 4K Camera Control Unit - Wifi, LENS 4K Camera Control Unit - Non-Wifi, LENS 4K Camera HeadAug 23, 2019
113 days to decisionK191177 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k191177/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	May 2, 2019
Decision date	Aug 23, 2019
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smith and Nephew, Inc.
Location	Andover, MA, US
Contact	Kathleen Solomon
510(k) history	7 submissions · 7 cleared · 2016-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191177/>. 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 May 26, 2026