

K201151 O-Mec 690 Series LaparoscopesJun 22, 2020
54 days to decisionK201151 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k201151/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Laparoscope, General & Plastic Surgery (GCJ) |
| Date received | Apr 29, 2020 |
| Decision date | Jun 22, 2020 |
| Days to decision | 54 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Omec Medical, Inc. |
| Location | San Jose, CA, US |
| Contact | Claire Nippress |
| 510(k) history | 1 submissions · 1 cleared · 2020-2020 |

REGULATORY CONSULTANT

| | |
|-----------------|-------------------------------|
| Consulting firm | Smith Associates/56345 |
| Contact | Yolanda Smith |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201151/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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