

K191678 IP ConverterJan 10, 2020
200 days to decisionK191678 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k191678/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Jun 24, 2019
Decision date	Jan 10, 2020
Days to decision	200 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sony Electronics, Inc.
Location	North Attleboro, MA, US
Contact	Shogo Obuchi
510(k) history	8 submissions · 8 cleared · 2009-2020

REGULATORY CONSULTANT

Consulting firm	Sony Corporation, Atsugi Technology Center
Contact	Tomomichi Iwasaka

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191678/> 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 June 18, 2026