

K203717 Processor VP-7000, Light Source BL-7000X, Image Processing Unit EX-0Jun 30, 2021
191 days to decisionK203717 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k203717/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Dec 21, 2020
Decision date	Jun 30, 2021
Days to decision	191 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fujifilm Corporaton
Location	Tokyo, JP
Contact	Randy Vader
510(k) history	6 submissions · 6 cleared · 2020-2023

REGULATORY CONSULTANT

Consulting firm	Fujifilm Medical Systems U.S.A, Inc.
Contact	Jeffrey Wan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203717/>; 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