

K213860 ArthroFree Wireless Surgical Camera SystemMar 23, 2022
103 days to decisionK213860 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213860/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Dec 10, 2021
Decision date	Mar 23, 2022
Days to decision	103 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Lazurite Holdings, LLC
Location	Cleveland, OH, US
Contact	Patrick Polito
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Mcra, LLC
Contact	Mike Goodson

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

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