

K212736 Canady Flex RoboWristNov 22, 2022
449 days to decisionK212736 · Product code: **GCJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k212736/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Aug 30, 2021
Decision date	Nov 22, 2022
Days to decision	449 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Us Medical Innovations, LLC
Location	Austin, TX, US
Contact	Jerome Canady
510(k) history	5 submissions · 5 cleared · 2011-2024

REGULATORY CONSULTANT

Consulting firm	Emergo Global Consulting, LLC
Contact	Michael A. Siano

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

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