

K212214 HandXSep 13, 2021
60 days to decisionK212214 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k212214/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Jul 15, 2021
Decision date	Sep 13, 2021
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Human Xtensions , Ltd.
Location	Netanya, IL
Contact	Maija Wallenstein
510(k) history	5 submissions · 5 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Randy J Prebula

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

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