

K230491 HandX™ Monopolar ScissorsMay 10, 2023
76 days to decisionK230491 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k230491/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Feb 23, 2023
Decision date	May 10, 2023
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230491/> 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