

K213209 EZ-TRAX Zimmer G7 Acetabular System / Taperloc Complete Hip System Containment DeviceDec 28, 2021
90 days to decisionK213209 · Product code: **KCT** · General Hospital
Source: <https://www.510kdatabase.net/k213209/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (KCT)
Date received	Sep 29, 2021
Decision date	Dec 28, 2021
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	K1 Medical, LLC
Location	Woodbridge, CT, US
Contact	Walt Oko
510(k) history	4 submissions · 4 cleared · 2019-2021

REGULATORY CONSULTANT

Consulting firm	Joseph Azary
Contact	Joseph Azary

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/k213209/> 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