

K240915 ZIEN IO Intraosseous Access SystemJul 2, 2024
90 days to decisionK240915 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k240915/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Apr 3, 2024
Decision date	Jul 2, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zien Medical Technologies, Inc.
Location	Salt Lake City, UT, US
Contact	Tim Nieman
510(k) history	2 submissions · 2 cleared · 2022-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240915/> 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 13, 2026