FDA 510(k) Premarket Notification

K240915 ZIEN IO Intraosseous Access System

CLEARED

Jul 2, 2024
90 days to decision

K240915 · Product code: **FMI** · General Hospital
Source: 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