

K191258 Intraosseous infusion deviceOct 23, 2019
166 days to decisionK191258 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k191258/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	May 10, 2019
Decision date	Oct 23, 2019
Days to decision	166 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Einstein Works, LLC
Location	Houston, TX, US
Contact	Linda Taylor
510(k) history	3 submissions · 3 cleared · 2019-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191258/> 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 27, 2026