

**K022415 BONE INJECTION GUN (B.I.G.) FOR PEDIATRICS,
MODEL 1ST**

Oct 11, 2002
79 days to decision

K022415 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k022415/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jul 24, 2002
Decision date	Oct 11, 2002
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Waismed, Ltd.
Location	Ra'Ananna, IL
Contact	DORIT WINITZ
510(k) history	7 submissions · 7 cleared · 1998-2021

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k022415/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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