

K981853 BONE INJECTION GUN (B.I.G.) DEVICENov 17, 1998
175 days to decisionK981853 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k981853/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	May 26, 1998
Decision date	Nov 17, 1998
Days to decision	175 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Waismed, Ltd.
Location	’Ananna, IL
Contact	AHAVA STEIN
510(k) history	7 submissions · 7 cleared · 1998-2021

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