

K954151 BIOACCESS BONE BIOPSY SYSTEMSep 15, 1995
10 days to decisionK954151 · Product code: **KNW** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k954151/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Sep 5, 1995
Decision date	Sep 15, 1995
Days to decision	10 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bioaccess, Inc.
Location	Silver Spring, MD, US
Contact	PETER J CARNES
510(k) history	3 submissions · 3 cleared · 1995-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k954151/> 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 July 1, 2026