

**K974158 ORION MEDICAL INC. DISPOSABLE BRAIN BIOPSY  
NEEDLE FOR STEROTACTIC GUIDED BIOPSY**

Dec 9, 1997  
36 days to decision

K974158 · Product code: **KNW** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k974158/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Nov 3, 1997
Decision date	Dec 9, 1997
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ortho Development Corp.</b>
Location	Draper, UT, US
Contact	CAROL FRASIER
510(k) history	45 submissions · 43 cleared · 1996-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k974158/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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