

**K112945 ELITECORE FULL CORE BIOPSY DEVICE
 18GAX10CM, 18GAX15CM, 18GAX20, WITH/HILITIER
 18GAX10CM , W/HILITER 18GAX15CM**

Nov 3, 2011
 30 days to decision

K112945 · Product code: **KNW** · Gastroenterology & Urology
 Source: <https://www.510kdatabase.net/k112945/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Instrument, Biopsy (KNW)
Date received	Oct 4, 2011
Decision date	Nov 3, 2011
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Inrad, Inc.
Location	Grand Rapids, MI, US
Contact	RYAN GOOSEN
510(k) history	4 submissions · 4 cleared · 2011-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k112945/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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