

**K863385 (ROTH)SPIRAL ROTATING PROSTATIC BIOPSY
NEEDLE**Nov 4, 1986
62 days to decisionK863385 · Product code: **KNN** · Physical Medicine
Source: <https://www.510kdatabase.net/k863385/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Components, Wheelchair (KNN)
Date received	Sep 3, 1986
Decision date	Nov 4, 1986
Days to decision	62 days
Third-party review	No

APPLICANT

Company	Cook Urological, Inc.
Location	Spencer, IN, US
Contact	FREDERICK D ROEMER
510(k) history	104 submissions · 102 cleared · 1986-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k863385/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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