

K921730 C-SECTION PACKJun 15, 1994
796 days to decisionK921730 · Product code: **KOH** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k921730/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Manual, General Obstetric-gynecologic (KOH)
Date received	Apr 10, 1992
Decision date	Jun 15, 1994
Days to decision	796 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Medikmark, Inc.
Location	Chicago, IL, US
Contact	RICHARD O WOOD
510(k) history	8 submissions · 4 cleared · 1992-1995

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k921730/> 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 May 26, 2026