FDA 510(k) Premarket Notification

K921730 C-SECTION PACK

CLEARED

Jun 15, 1994
796 days to decision

K921730 · Product code: **KOH** · Obstetrics & Gynecology
Source: 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