FDA 510(k) Premarket Notification

K963692 VERDICT PCP

CLEARED

Dec 10, 1996
85 days to decision

K963692 · Product code: **LCM** · Toxicology
Source: https://www.510kdatabase.net/k963692/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Phencyclidine (LCM)
Date received	Sep 16, 1996
Decision date	Dec 10, 1996
Days to decision	85 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Editek, Inc.**
Location	Burlington, NC, US
Contact	CAROLE GOLDEN
510(k) history	7 submissions · 7 cleared · 1994-1996

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k963692/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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