FDA 510(k) Premarket Notification

K980888 GLYCACOR

CLEARED

Aug 13, 1998
157 days to decision

K980888 · Product code: **LCP** · Chemistry
Source: https://www.510kdatabase.net/k980888/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Mar 9, 1998
Decision date	Aug 13, 1998
Days to decision	157 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Exocell, Inc.**
Location	Philadelphia, PA, US
Contact	MARGO P COHEN
510(k) history	5 submissions · 5 cleared · 1989-1998

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k980888/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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