FDA 510(k) Premarket Notification

K883269 PRL-QUANT

CLEARED

Sep 13, 1988
41 days to decision

K883269 · Product code: **CFT** · Chemistry
Source: https://www.510kdatabase.net/k883269/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Prolactin (lactogen) (CFT)
Date received	Aug 3, 1988
Decision date	Sep 13, 1988
Days to decision	41 days
Third-party review	No

APPLICANT

Company	**Leeco Diagnostics, Inc.**
Location	Mchenry, IL, US
Contact	LEE, PH.D.
510(k) history	49 submissions · 49 cleared · 1979-1989