FDA 510(k) Premarket Notification

K860003 LEECO TESTOSTERONE DIAGNOSTIC KIT

CLEARED

Mar 17, 1986
74 days to decision

K860003 · Product code: **CDZ** · Chemistry
Source: https://www.510kdatabase.net/k860003/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Testosterones And Dihydrotestosterone (CDZ)
Date received	Jan 2, 1986
Decision date	Mar 17, 1986
Days to decision	74 days
Third-party review	No

APPLICANT

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