FDA 510(k) Premarket Notification

K803001 LEECO TESTO-QUANT DIAGNOSTIC KIT

CLEARED

Jan 2, 1981
38 days to decision

K803001 · Product code: **CDZ** · Chemistry
Source: https://www.510kdatabase.net/k803001/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Testosterones And Dihydrotestosterone (CDZ)
Date received	Nov 25, 1980
Decision date	Jan 2, 1981
Days to decision	38 days
Third-party review	No

APPLICANT

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