FDA 510(k) Premarket Notification

K895666 BUN (KINETIC)

CLEARED

Oct 27, 1989
37 days to decision

K895666 · Product code: **CDQ** · Chemistry
Source: https://www.510kdatabase.net/k895666/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urease And Glutamic Dehydrogenase, Urea Nitrogen (CDQ)
Date received	Sep 20, 1989
Decision date	Oct 27, 1989
Days to decision	37 days
Third-party review	No

APPLICANT

Company	**Boehringer Mannheim Corp.**
Location	Mchenry, IL, US
Contact	CHERI EMMONS
510(k) history	340 submissions · 340 cleared · 1976-1999