

K990980 BUN, MODEL BU 104-01May 25, 1999
63 days to decisionK990980 · Product code: **CDQ** · Chemistry
Source: <https://www.510kdatabase.net/k990980/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urease And Glutamic Dehydrogenase, Urea Nitrogen (CDQ)
Date received	Mar 23, 1999
Decision date	May 25, 1999
Days to decision	63 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	A.P. Total Care, Inc.
Location	Bridgeport, CT, US
Contact	LUIS P LEON
510(k) history	18 submissions · 18 cleared · 1999-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k990980/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 30, 2026