

K041051 RAICHEM BUN RATE REAGENT (LIQUID)Jun 30, 2004
72 days to decisionK041051 · Product code: **CDQ** · Chemistry
Source: <https://www.510kdatabase.net/k041051/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urease And Glutamic Dehydrogenase, Urea Nitrogen (CDQ)
Date received	Apr 19, 2004
Decision date	Jun 30, 2004
Days to decision	72 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Hemagen Diagnostics, Inc.
Location	Waltham, MA, US
Contact	JAMES J MILLER
Website	http://www.hemagen.com/
510(k) history	52 submissions · 52 cleared · 1986-2004

Hemagen Diagnostics, Inc. was founded in 1985 by scientists from Boston University School of Medicine. The company provides clinical diagnostic solutions specializing in immunology devices for autoimmune and infectious disease testing. Hemagen offers gold standard IFA products, ELISA, HA, and point-of-care testing formats for human and veterinary diagnostics. Hemagen has received FDA 510(k) clearances from total submissions since its first clearance in 1986. The company's regulatory portfolio focuses on immunology devices, including antibody detection kits, autoimmune scr...
