

K012649 RAICHEM BUN RATE REAGENTOct 15, 2001
63 days to decisionK012649 · Product code: **CDQ** · Chemistry
Source: <https://www.510kdatabase.net/k012649/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urease And Glutamic Dehydrogenase, Urea Nitrogen (CDQ)
Date received	Aug 13, 2001
Decision date	Oct 15, 2001
Days to decision	63 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Hemagen Diagnostics, Inc.
Location	Waltham, MA, US
Contact	JOSE A MONTANEZ
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...
