

**K011126 RAICHEM CREATININE URINE STANDARD**May 2, 2001  
19 days to decisionK011126 · Product code: **JIT** · Chemistry  
Source: <https://www.510kdatabase.net/k011126/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Calibrator, Secondary (JIT)
Date received	Apr 13, 2001
Decision date	May 2, 2001
Days to decision	19 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Hemagen Diagnostics, Inc.</b>
Location	Waltham, MA, US
Contact	JOSE A MONTANEZ
Website	<a href="http://www.hemagen.com/">http://www.hemagen.com/</a>
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...

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