

K061879 SDI CA480 CLINICAL CHEMISTRY SYSTEMDec 15, 2006
165 days to decisionK061879 · Product code: **CFR** · Chemistry
Source: <https://www.510kdatabase.net/k061879/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hexokinase, Glucose (CFR)
Date received	Jul 3, 2006
Decision date	Dec 15, 2006
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary
Other names	SATURNO 300 CLINICAL CHEMISTRY SYSTEM

APPLICANT

Company	Hemodiagnostica, LLC
Location	Johns Island, SC, US
Contact	Bruno Borganti
510(k) history	1 submissions · 1 cleared · 2006-2006

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