

K023396 AMYLASE EPS-G7 (LIQUID) REAGENT SET, (HITACHI ANALYZERS)

Dec 23, 2002
75 days to decision

K023396 · Product code: **CIJ** · Chemistry
Source: <https://www.510kdatabase.net/k023396/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Saccharogenic, Amylase (CIJ)
Date received	Oct 9, 2002
Decision date	Dec 23, 2002
Days to decision	75 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Pointe Scientific, Inc.,
Location	Mchenry, IL, US
Contact	RON JAMISON
510(k) history	74 submissions · 74 cleared · 1981-2007

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Device record: <https://www.510kdatabase.net/k023396/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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