

**K011145 MODIFICATION TO REFLOTRON AMYLASE, CAT.
1200658**Jun 25, 2001
91 days to decisionK011145 · Product code: JFJ · Chemistry
Source: <https://www.510kdatabase.net/k011145/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	Mar 26, 2001
Decision date	Jun 25, 2001
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	JENNIFER TRIBETT
510(k) history	264 submissions · 263 cleared · 1999-2013

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