

**K182474 alpha-AMYLASE DIRECT, alpha-AMYLASE EPS, alpha-AMYLASE PANCREATIC, BILIRUBIN DIRECT, BILIRUBIN TOTAL**

May 2, 2019  
234 days to decision

K182474 · Product code: **JFJ** · Chemistry  
Source: <https://www.510kdatabase.net/k182474/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	Sep 10, 2018
Decision date	May 2, 2019
Days to decision	234 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Biosystems S.A.</b>
Location	Barcelona, ES
Contact	Noelia Gil
510(k) history	4 submissions · 4 cleared · 2018-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k182474/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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