

**K170901 ALBUMIN, ALKALINE PHOSPHATASE (ALP)-AMP,
GLUCOSE-HEXOKINASE, BA400**Apr 13, 2018
382 days to decisionK170901 · Product code: **CIX** · Chemistry
Source: <https://www.510kdatabase.net/k170901/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bromocresol Green Dye-binding, Albumin (CIX)
Date received	Mar 27, 2017
Decision date	Apr 13, 2018
Days to decision	382 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Biosystems S.A.
Location	Barcelona, ES
Contact	Teresa Maria Cortes
510(k) history	4 submissions · 4 cleared · 2018-2020

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