

K192730 CALCIUM-CRESOLPHTHALEIN, GLUCOSE, UREA/BUN-UV

Sep 9, 2020
348 days to decision

K192730 · Product code: **CHW** · Chemistry
Source: <https://www.510kdatabase.net/k192730/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Titrimetric With Edta And Indicator, Calcium (CHW)
Date received	Sep 27, 2019
Decision date	Sep 9, 2020
Days to decision	348 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k192730/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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