FDA 510(k) Premarket Notification

CLEARED

K190298 DxA 5000, DxI 800 Access Immunoassay System, Access Ferritin, Access Folate, Access TSH (3rd IS), Access Vitamin B12

Oct 4, 2019
235 days to decision

K190298 · Product code: **CDD** · Chemistry
Source: https://www.510kdatabase.net/k190298/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioassay, Vitamin B12 (CDD)
Date received	Feb 11, 2019
Decision date	Oct 4, 2019
Days to decision	235 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Beckman Coulter Biomedical GmbH**
Location	Munich, DE
Contact	Amanda Brown
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k190298/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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