

K181894 TOF-Cuff monitorMay 9, 2019
297 days to decisionK181894 · Product code: **DXN** · AnesthesiologySource: <https://www.510kdatabase.net/k181894/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Jul 16, 2018
Decision date	May 9, 2019
Days to decision	297 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Rgb Medical Devices SA
Location	Madrid, ES
Contact	Ricardo Ruiz
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181894/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026