

K231620 Nuubo SmartAug 1, 2023
60 days to decisionK231620 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k231620/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Jun 2, 2023
Decision date	Aug 1, 2023
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Smart Solutions Technologies SL
Location	Madrid, ES
Contact	Borja Gonzal Vez
510(k) history	2 submissions · 2 cleared · 2018-2023

REGULATORY CONSULTANT

Consulting firm	Enem Consulting, LLC
Contact	Nandini Murthy

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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