

K212045 SoftSpotSep 28, 2021
90 days to decisionK212045 · Product code: **QQO** · Neurology
Source: <https://www.510kdatabase.net/k212045/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cranial Measurement Software (QQO)
Date received	Jun 30, 2021
Decision date	Sep 28, 2021
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pediametrix, Inc.
Location	Rockville, MD, US
Contact	Joshua D Levin
510(k) history	1 submissions · 1 cleared · 2021-2021

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