

K231688 ImPACT Version 4Sep 16, 2023
99 days to decisionK231688 · Product code: **POM** · Neurology
Source: <https://www.510kdatabase.net/k231688/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computerized Cognitive Assessment Aid For Concussion (POM)
Date received	Jun 9, 2023
Decision date	Sep 16, 2023
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Impact Applications, Inc.
Location	Pittsburgh, PA, US
Contact	Michael Zagorski
510(k) history	6 submissions · 5 cleared · 2016-2023

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