

K202485 ImPACT Version 4Dec 25, 2020
116 days to decisionK202485 · Product code: **POM** · Neurology
Source: <https://www.510kdatabase.net/k202485/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computerized Cognitive Assessment Aid For Concussion (POM)
Date received	Aug 31, 2020
Decision date	Dec 25, 2020
Days to decision	116 days
Third-party review	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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