

K192549 Byteflies KitJun 22, 2020
279 days to decisionK192549 · Product code: **OMC** · Neurology
Source: <https://www.510kdatabase.net/k192549/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reduced- Montage Standard Electroencephalograph (OMC)
Date received	Sep 17, 2019
Decision date	Jun 22, 2020
Days to decision	279 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Byteflies NV
Location	Antwerp, BE
Contact	Benjamin Vandendriessche
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Medicsense USA
Contact	Benjamin Vandendriessche

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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