

K223140 AEON-C™ Stand Alone SystemDec 20, 2022
77 days to decisionK223140 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k223140/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE) |
| Date received | Oct 4, 2022 |
| Decision date | Dec 20, 2022 |
| Days to decision | 77 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Dio Medical, Inc. |
| Location | East Norriton, PA, US |
| Contact | Milan George |
| 510(k) history | 1 submissions · 1 cleared · 2022-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223140/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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