

**K233580 A Breathing System (ABS)**Aug 1, 2024  
268 days to decisionK233580 · Product code: **HCC** · Neurology  
Source: <https://www.510kdatabase.net/k233580/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Device, Biofeedback (HCC)          |
| Date received         | Nov 7, 2023                        |
| Decision date         | Aug 1, 2024                        |
| Days to decision      | 268 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Deepwell Dtx, Inc.</b>             |
| Location       | Seattle, WA, US                       |
| Contact        | Jeff Harris                           |
| 510(k) history | 1 submissions · 1 cleared · 2024-2024 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233580/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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