

K213697 ORiGO SystemOct 31, 2022
342 days to decisionK213697 · Product code: **HBC** · Neurology
Source: <https://www.510kdatabase.net/k213697/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Motor, Drill, Electric (HBC) |
| Date received | Nov 23, 2021 |
| Decision date | Oct 31, 2022 |
| Days to decision | 342 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Bien-Air Surgery SA |
| Location | Le Noirmont, CH |
| Contact | Jonas Guerdat |
| 510(k) history | 5 submissions · 5 cleared · 2009-2022 |

REGULATORY CONSULTANT

| | |
|-----------------|----------------------------------|
| Consulting firm | Ken Block Consulting, LLC |
| Contact | Akiko Dohi |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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