

K041215 CRANIAL HELMETSep 9, 2004
122 days to decisionK041215 · Product code: **MVA** · Neurology
Source: <https://www.510kdatabase.net/k041215/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Orthosis, Cranial (MVA) |
| Date received | May 10, 2004 |
| Decision date | Sep 9, 2004 |
| Days to decision | 122 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Otto Bock Healthcare LP |
| Location | Minneapolis, MN, US |
| Contact | SHELLEY STOCKMAN |
| 510(k) history | 17 submissions · 17 cleared · 2003-2022 |

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