

K040864 CRANIOFIX AND CRANIOFIX2 TITANIUM CLAMP SYSTEMJun 17, 2004
76 days to decisionK040864 · Product code: **GXN** · Neurology
Source: <https://www.510kdatabase.net/k040864/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Plate, Cranioplasty, Preformed, Non-alterable (GXN) |
| Date received | Apr 2, 2004 |
| Decision date | Jun 17, 2004 |
| Days to decision | 76 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Aesculap |
| Location | Center Valley, PA, US |
| Contact | KATHY A RACOSKY |
| 510(k) history | 10 submissions · 10 cleared · 2003-2010 |

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