

K072601 OSTEOSYMBIONICS PATIENT SPECIFIC CRANIAL IMPLANTDec 10, 2007
87 days to decisionK072601 · Product code: **GXP** · Neurology
Source: <https://www.510kdatabase.net/k072601/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Methyl Methacrylate For Cranioplasty (GXP) |
| Date received | Sep 14, 2007 |
| Decision date | Dec 10, 2007 |
| Days to decision | 87 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Osteosymbionics, LLC |
| Location | Cleveland, OH, US |
| Contact | CYNTHIA M BROGAN |
| 510(k) history | 4 submissions · 4 cleared · 2007-2014 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k072601/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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