

K182711 Customized Craniofacial Implant (CCI), Customized Skull Implant (CSI)May 21, 2019
236 days to decisionK182711 · Product code: **GWO** · Neurology
Source: <https://www.510kdatabase.net/k182711/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Plate, Cranioplasty, Preformed, Alterable (GWO) |
| Date received | Sep 27, 2018 |
| Decision date | May 21, 2019 |
| Days to decision | 236 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Kelyniam Global, Inc. |
| Location | New Britain, CT, US |
| Contact | Eric Boyea |
| 510(k) history | 4 submissions · 4 cleared · 2011-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182711/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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