FDA 510(k) Premarket Notification

# K171507 CustomizedBone Service

**CLEARED**

Sep 1, 2017
101 days to decision

K171507 · Product code: **GXN** · Neurology
Source: https://www.510kdatabase.net/k171507/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Plate, Cranioplasty, Preformed, Non-alterable (GXN) |
| Date received | May 23, 2017 |
| Decision date | Sep 1, 2017 |
| Days to decision | 101 days |
| Third-party review | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **Fin-Ceramica Faenza S.P.A.** |
| Location | Faenza, IT |
| Contact | Marina Monticelli |
| 510(k) history | 5 submissions · 5 cleared · 2016-2024 |