

K982101 SHELHIGH NO-REACT DURA SHIELDMay 2, 2000
687 days to decisionK982101 · Product code: **GXQ** · Neurology
Source: <https://www.510kdatabase.net/k982101/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dura Substitute (GXQ) |
| Date received | Jun 15, 1998 |
| Decision date | May 2, 2000 |
| Days to decision | 687 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Shelhigh, Inc. |
| Location | Union, NJ, US |
| Contact | SHLOMO GABBAY |
| 510(k) history | 8 submissions · 8 cleared · 1997-2003 |

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