

K161654 NuFACE Gel PrimerDec 30, 2016
198 days to decisionK161654 · Product code: **GYB** · Neurology
Source: <https://www.510kdatabase.net/k161654/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Media, Electroconductive (GYB) |
| Date received | Jun 15, 2016 |
| Decision date | Dec 30, 2016 |
| Days to decision | 198 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Carol Cole Company |
| Location | La Jolla, CA, US |
| Contact | Merle Kovacic |
| 510(k) history | 6 submissions · 6 cleared · 2007-2016 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161654/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 2, 2026