

K853442 MODEL 804 (TENS)Dec 9, 1985
115 days to decisionK853442 · Product code: **GZJ** · Neurology
Source: <https://www.510kdatabase.net/k853442/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ) |
| Date received | Aug 16, 1985 |
| Decision date | Dec 9, 1985 |
| Days to decision | 115 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|--|
| Company | Oriental Medical Supplies, Inc. |
| Location | Braintree, MA, US |
| Contact | THOMAS RIIHIMAKI |
| 510(k) history | 6 submissions · 6 cleared · 1985-1989 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k853442/>; 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 30, 2026