

K962951 MODEL HS-2 TENS DEVICEAug 6, 1997
376 days to decisionK962951 · Product code: **GZJ** · Neurology
Source: <https://www.510kdatabase.net/k962951/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	Jul 26, 1996
Decision date	Aug 6, 1997
Days to decision	376 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Technalithics Laboratories, Inc.
Location	Waco, TX, US
510(k) history	1 submissions · 1 cleared · 1997-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k962951/>, 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