

K010209 ELECTRO-NERVE STIMULATOR TENS, MODEL HE-DIGITALJun 12, 2001
140 days to decisionK010209 · Product code: **GZJ** · Neurology
Source: <https://www.510kdatabase.net/k010209/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	Jan 23, 2001
Decision date	Jun 12, 2001
Days to decision	140 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Biomedical Life Systems, Inc.
Location	Walker, MI, US
Contact	RICHARD SAXON
510(k) history	35 submissions · 35 cleared · 1984-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k010209/> 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 May 30, 2026