K010209 ELECTRO-NERVE STIMULATOR TENS, MODEL HE-DIGITAL

CLEARED

Jun 12, 2001
140 days to decision

K010209 · 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