FDA 510(k) Premarket Notification

CLEARED

K010008 AXXESS SPINAL CORD STIMULATION LEAD, MODEL 8000 SERIES, INCLUDING 80XX, 81XX, AND 82XX

Jul 16, 2001
195 days to decision

K010008 · Product code: **GZB** · Neurology
Source: https://www.510kdatabase.net/k010008/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Spinal-cord, Implanted (pain Relief) (GZB)
Date received	Jan 2, 2001
Decision date	Jul 16, 2001
Days to decision	195 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Micronet Medical, Inc.**
Location	White Bear Lake,, MN, US
Contact	CHARLES LEHMAN
510(k) history	1 submissions · 1 cleared · 2001-2001