FDA 510(k) Premarket Notification

K040568 POLYETHER URETHANE MATERIAL CHANGE IN NEUROSTIMULATION LEADS

CLEARED

Mar 25, 2004
21 days to decision

K040568 · Product code: **GZB** · Neurology
Source: https://www.510kdatabase.net/k040568/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Spinal-cord, Implanted (pain Relief) (GZB)
Date received	Mar 4, 2004
Decision date	Mar 25, 2004
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Vascular**
Location	Walker, MI, US
Contact	Doug Atkins
510(k) history	475 submissions · 453 cleared · 1977-2023