FDA 510(k) Premarket Notification

CLEARED

K952459 MEDTRONIC MODEL 3991, 3991C, 3992, 3992C, 3993, 3993C, 3994, 3994C LEADS OR, TRANSVERSE TRIPOLAR LEADS OR, TTL

Aug 30, 1995
96 days to decision

K952459 · Product code: **GZB** · Neurology
Source: https://www.510kdatabase.net/k952459/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Spinal-cord, Implanted (pain Relief) (GZB)
Date received	May 26, 1995
Decision date	Aug 30, 1995
Days to decision	96 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k952459/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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