FDA 510(k) Premarket Notification

K011702 VERTIS PNT CONTROL UNIT, VERTIS PNT SAFEGUIDE KIDS, MODELS CU100, SGXXX

CLEARED

Dec 21, 2001
203 days to decision

K011702 · Product code: **NHI** · Neurology
Source: https://www.510kdatabase.net/k011702/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Electrical, Percutaneous (pens), For Pain Relief (NHI)
Date received	Jun 1, 2001
Decision date	Dec 21, 2001
Days to decision	203 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Vertis Neuroscience, Inc.**
Location	Seattle, WA, US
Contact	LORI GLASTETTER
510(k) history	2 submissions · 2 cleared · 2001-2002