FDA 510(k) Premarket Notification

K071113 RT300-S, MODEL FA100052, RT300-SP (PEDIATRIC VERSION), MODEL FA100053

CLEARED

Jul 5, 2007
76 days to decision

K071113 · Product code: **GZI** · Neurology
Source: https://www.510kdatabase.net/k071113/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Neuromuscular, External Functional (GZI)
Date received	Apr 20, 2007
Decision date	Jul 5, 2007
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Restorative Therapies, Inc.**
Location	Baltimore, MD, US
Contact	ANDREW BARRISKILL
510(k) history	10 submissions · 10 cleared · 2005-2017