FDA 510(k) Premarket Notification

K071486 RT300-S, RT300-SP (PEDIATRIC VERSION), MODEL FA100052, FA100053

CLEARED

Sep 10, 2007
103 days to decision

K071486 · Product code: **GZI** · Neurology
Source: https://www.510kdatabase.net/k071486/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Neuromuscular, External Functional (GZI)
Date received	May 30, 2007
Decision date	Sep 10, 2007
Days to decision	103 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