FDA 510(k) Premarket Notification

K152676 FD TENS 2090, FD TENS 2095

CLEARED

Jan 22, 2016
126 days to decision

K152676 · Product code: **GZJ** · Neurology
Source: https://www.510kdatabase.net/k152676/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	Sep 18, 2015
Decision date	Jan 22, 2016
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Fuji Dynamics , Ltd.**
Location	Hong Kong, CN
Contact	MAN CHUNG MAN
510(k) history	5 submissions · 5 cleared · 2011-2016