FDA 510(k) Premarket Notification

K181645 StimaWELL 120MTRS

CLEARED

Aug 13, 2020
783 days to decision

K181645 · Product code: **GZJ** · Neurology
Source: https://www.510kdatabase.net/k181645/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	Jun 22, 2018
Decision date	Aug 13, 2020
Days to decision	783 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Pierenkemper GmbH**
Location	Ehringshausen, DE
Contact	Thorsten Reichel
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Emergo Global Consulting**
Contact	Andre Kindsvater

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov