FDA 510(k) Premarket Notification

CLEARED

K170205 Low-Frequency Therapy Instrument /Model: KTR-201, KTR-202, KTR-203

May 11, 2017
108 days to decision

K170205 · Product code: **NUH** · Neurology
Source: https://www.510kdatabase.net/k170205/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Jan 23, 2017
Decision date	May 11, 2017
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Kentro Medical Electronics Co., Ltd.**
Location	Shenzhen, CN
Contact	Zewu Zhang
510(k) history	10 submissions · 10 cleared · 2017-2024