FDA 510(k) Premarket Notification

K232441 Unipro (K-UNIPRO-US)

CLEARED

Aug 30, 2024
382 days to decision

K232441 · Product code: **GZJ** · Neurology
Source: https://www.510kdatabase.net/k232441/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	Aug 14, 2023
Decision date	Aug 30, 2024
Days to decision	382 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Tenscare, Ltd.**
Location	Timperley, Cheshire, GB
Contact	Saskia Eldridge-Hinmers
510(k) history	13 submissions · 13 cleared · 2001-2024