

K181102 ThermaCare Quick Therapy TENSSep 15, 2018
142 days to decisionK181102 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k181102/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Apr 26, 2018
Decision date	Sep 15, 2018
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pfizer, Inc.
Location	Mchenry, IL, US
Contact	Nicola Romano
510(k) history	30 submissions · 30 cleared · 1977-2018

Pfizer, Inc. is an American multinational pharmaceutical and biotechnology corporation headquartered in Manhattan, New York City. Founded in 1849, Pfizer is one of the oldest pharmaceutical companies in North America. Pfizer's FDA 510(k) regulatory record includes cleared devices from total submissions, spanning 1977 to 2018. The company's device portfolio demonstrates strength in orthopedic devices, including surgical implants and fixation systems. This regulatory activity is now historical, with no clearances recorded in the past five years. The company's cleared device...

REGULATORY CONSULTANT

Consulting firm	Shenzhen Dongdixin Technology Co., Ltd.
Contact	Siping Yuan

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

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Device record: <https://www.510kdatabase.net/k181102/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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