

**K183215 Focus TENS Therapy, Model PM710-M/-L**Sep 7, 2019  
292 days to decisionK183215 · Product code: **NUH** · Neurology  
Source: <https://www.510kdatabase.net/k183215/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Nov 19, 2018
Decision date	Sep 7, 2019
Days to decision	292 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Omron Healthcare, Inc.</b>
Location	Vernon Hills, IL, US
Contact	Renee Thornborough
510(k) history	68 submissions · 67 cleared · 1991-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183215/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026