

**K203337 PainTB, PainTJ**Feb 11, 2022  
456 days to decisionK203337 · Product code: **NHN** · Physical Medicine  
Source: <https://www.510kdatabase.net/k203337/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Light Based Laser Non-thermal Instrument With Non-heating Effect For Adjunctive Use In Pain Therapy (NHN)
Date received	Nov 12, 2020
Decision date	Feb 11, 2022
Days to decision	456 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Ptech Co., Ltd.</b>
Location	Pyeongtaek-Si, KR
Contact	Yosung Choi
510(k) history	1 submissions · 1 cleared · 2022-2022

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203337/> Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026