February 11, 2022

Ptech Co., Ltd.
Yosung Choi
CEO
35, Wondogok-gil, Poseung-eup
Pyeongtaek-si, Gyeonggi-do 13449
Korea, South

Re: K203337
Trade/Device Name: PainTB, PainTJ
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: NHN
Dated: October 13, 2020
Received: January 10, 2022

Dear Yosung Choi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203337

Device Name
PainTB, PainTJ

Indications for Use *(Describe)*
Pain TB and Pain TJ Laser systems are indicated for adjunctive use in the temporary relief of low-back pain and wrist pain associated with Carpal Tunnel Syndrome.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) summary

The assigned 510(k) number: K203337

1. Date Prepared: February 11, 2022

2. Application

Company Name: Ptech Co., Ltd.
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3. Submission Correspondent

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4. Proposed Device Identification

Proprietary Name: PainTB, PainTJ
Model Name:PMD-PB230, PMD-PJ230
Classification name: Infrared Lamp
Device Class: Class II
Regulation number: 21 CFR 890.5500
Product Code: NHN

5. Predicate devices

Manufacturer: THØR International Ltd.
Brand Name: THØR DDII 830CL3
FDA 510(K) number: K030226

6. Indication for use

PainTB and PainTJ Laser systems are indicated for adjunctive use in the temporary relief of low-back pain and wrist pain associated with Carpal Tunnel Syndrome.

7. Device description

PainTB and PainTJ can be used repeatedly and uses semiconductor lasers to generate three wavelengths of light at 670nm, 830nm and 910nm. In general, this device irradiates to the pain area with a laser beam to relieve pain. It can also be controlled via a dedicated app on your smartphone, allowing you to monitor when and how much you have used it.

Product name	PainTB/PainTB
Model name	PMD-PB230/ PMD-PJ230
Product Code	NHN
Regulation Number	21 CFR 890.5500
Device Class	Class II
Rated power of recharging adapter	Input: 100 - 240V, 50/60Hz, 0.6 - 0.3A Output: DC5V, 1.2A
Rated power of embedded battery	DC 3.7V 2000mAh lithium polymer
Protection type and degree against electric shock	Class II and internally powered source device, Type BF applied part
Protection against hazardous penetration of water and particles	IP22
Operating conditions	Temperature: 10℃ - 40℃, Humidity: 30 - 85% R.H., Atmospheric pressure: 700 - 1,060 hPa
Transport and storage conditions	Temperature: -10℃ - 50℃, Humidity: 30 - 85% R.H., Atmospheric pressure: 700 - 1,060 hPa
Weight of main body/recharging adapter	PMD-PB230:250g, PMD-PJ230:201g Adapter: 70g
Size of main body	PMD-PB230: 152mm x 245mm (thickness 15mm) PMD-PJ230:106mm x 136mm (thickness 40mm)
Laser module	Model Name: COB-CO-1509A Wavelength: 670nm, 830nm, 910nm No. of laser diodes per module: 3 per wavelength, total 9 No. of modules: PMD-PB230 8, PMD-PJ230 6 Laser class: 3B
Laser operating time	20/40/60 minutes

Packaging	1 Set
Country of origin	Republic of Korea

8. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The mechanism for pain treatment using Non-heating Infrared ramp has been studied for a long time, and various products have cleared FDA 510(K) and are being used as medical devices for treatment. Our product have three wavelength's diode laser(670nm, 839nm, 910nm) and they are cross irradiated so don't be overlay to another wavelength when it is working. Also, each wavelength is generally used in pain treatment, and we can easily find similar product in the market.

The following is the result of comparing our product with the similar product in clinical literatures chosen. At the technical aspect, light sources and wavelength optical power were compared. The similar product used diode Laser and its wavelength was 830nm so it is same wave length as ours. Optical power of similar product is 30mW and our 830nm is 24.1mW so it is within the acceptable range. Thus, this product and our product have technical equivalence.
In addition, the application range and the effect of the product were compared at the clinical aspect. The predicate device was used at pain treatment and reduced pain so it is same as ours. Thus, this product and our product have clinical equivalence.

There is some gap in comparison with similar products because our product have 2 more wavelength laser used. Although 830nm is major and other 670nm and 910nm laser is lower power for supporting performance of the treatment, it is showing gap with predicate device.

No.	Item	device #1	Our product
1	Manufacturer	Thor International	Ptech Co.,Ltd.
2	Model Name 510(k)#	Thor DD2 830cl3 (K030226)	PMD-PB230, PMD-PJ230 (K203337)
3	Laser Class	Not Publicly Available	3B
4	Regulation Number	21 CFR 890.5500	21 CFR 890.5500
5	Regulatory class	2	2
6	FDA Product code	NHN	NHN
7	IFU	The TH0R DDII 83OCL3 Laser System is a non-heating infrared lamp and is indicated for adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome	PainTB and PainTJ Laser systems are indicated for adjunctive use in the temporary relief of low-back pain and wrist pain associated with Carpal Tunnel Syndrome.
8	CE status	CE certified	CE certified

9	Picture		Not Publicly Available	
10	Technical	Light sources used	Diode	Diode
11		Operation mode	Not Publicly Available	pulse
12		Wavelengths used	830nm	670nm, 830nm, 910nm Cross irradiate
13		Number of Diode	3	[PMD-PB230] 670nm: .8 830nm:8 910nm: 8 [PMD-PJ230] 670nm: .6 830nm:6 910nm: 6
14		Treatment time	Not Publicly Available	Depends on the therapist choice
15		Power supply	Not Publicly Available	Input:AC100-240V Output: DC 5V, 1.2A
16		Average Output	830nm:3X30mW	[PMD-PB230] 670nm: .8x4.5mW 830nm:8x24.1mW 910nm: 8x3mW Total 252.8mW [PMD-PJ230] 670nm: .6x4.5mW 830nm:6x24.1mW 910nm: 6x3mW Total 188.6mW
17		Spot Size	Not Publicly Available	1.7mm (Circular)
18		Energy Fluency (mW/cm2, mJ/cm2))	Not Publicly Available	670nm: .66mW/cm2 830nm: 354mW/cm2 910nm: 44mW/cm2
19	Clinical	Application	Pain Area(hand & wrist)	Pain area (low back, wrist)

9. Performance standard

Our products voluntarily comply with the standards below.

General Safety standard:	IEC 60601-1:2005/AMD1:2012
EMC	60601-1-2:2014
Usability:	IEC 60601-1-6:2010,
Home Health Care:	AMD1:2013 IEC
Medical Laser Equipment:	60601-1-11:2015
Safety of laser products:	IEC 60601-2-22:2007 +A1:2012
Biological evaluation(Cytotoxicity):	IEC 60825-1:2014
	ISO 10993-5:2009

Biological evaluation(Skin Sensitization):	ISO 10993-10:2010
Biological evaluation(Skin Irritation):	ISO 10993-10:2010

10. Summary of Clinical Information

The PainTB was evaluated in a prospective, rater blind, randomized study that compared the "Active" Laser with a "Mock" Laser. The single-center study was conducted in the South Korea. In the test, 60 adult patients of back pain whose VAS score is 4 or higher are recruited as subjects, PainTB alone test and exercise treatment combined with PainTB use and “Mock” device use are conducted, and VAS measurement has used as pain level scale.

Clinical Data Analysis and Results

Statistical analyses (one-way ANOVA) were performed by generally accepted statistical techniques to evaluate the differences between the VAS scores before and after treatment follow up for patients in Group B (Active Laser + exercise treatment) and Group C (Mock Laser + exercise treatment).

The statistical analyses of the data demonstrate that the difference between the two treatment groups over time is statistically significant (p-value < 0.05).

No adverse effects from the laser treatments were observed by the principal Investigators during the clinical investigational study.

11. Conclusion

In conclusion, PainTB/PainTJ and predicate device are products with the same technical characteristics and IFU that share the same. Although there are some gap, with reviewing the submitted clinical report, it can be seen that the gap does not affect basic effectiveness and safety equivalence of the products, it is also effective for low back pain.