August 10, 2022

Cytonsys Inc
Li-Da Huang
President
7801 N. Lamar Blvd, ste C-59
Austin, Texas 78752

Re: K213524
Trade/Device Name: CytonPro-5000
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: ILY
Dated: October 28, 2021
Received: November 3, 2021

Dear Li-Da Huang:

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)*
K213524

Device Name
CytonPro-5000

Indications for Use *(Describe)*
The model CytonPro-5000 laser emits energy in the infrared spectrum to provide topical heating to elevate tissue temperature for temporary relief of muscle and joint pain, muscle spasm and stiffness associated with arthritis. It also increases blood circulation and relaxes muscle tissue.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

1. SUBMITTER INFORMATION

Name: CytonSys Inc.
7801 N. Lamar Blvd, Suite C-59
Austin TX 78752
Tel: (512)572-0080

Date Prepared: August 9, 2022

2. DEVICE

Name of Device: CytonPro-5000
Common or Usual Name: Infrared Lamp
Classification Name: Infrared Lamp (21 CFR 890.5500)
Regulation Number: II
Product Code: ILY

3. PREDICATE DEVICE

a. Cell Gen CG-4000 laser – cleared under K080084 dated April 21, 2008

4. INDICATIONS FOR USE

The model CytonPro-5000 laser emits energy in the infrared spectrum to provide topical heating to elevate tissue temperature for temporary relief of muscle and joint pain, muscle spasm and stiffness associated with arthritis. It also increases blood circulation and relaxes muscle tissue.

5. DEVICE DESCRIPTION

a. Device Identification:
The CytonPro-5000 laser is a non-invasive, diode laser system consisting of an enclosure which contains the control unit and a treatment probe connected by an optic fiber.
b. Device Characteristics:
- Software

c. Environment of Use: professional healthcare facility
d. Brief Written Description of the Device:
- Explanation of how the device works/principle of operation:
  (a). Connect the CytonPro-5000 with your laptop.
  (b). Switch the toggle switch on the back panel.
  (c). Insert the key on the back panel too, and turn it on (horizontal).

(d). Put the CD into the CD-ROM, and open the folder to view files.

(e). Double click the "CytonPro" icon, and run the software (for detailed operation, please refer to the Operator's manual).

- Mechanism of action: the laser beam emitted by the CytonPro-5000 Laser System is a wavelength combination of 1064nm and 650nm (pointing diode). The 1064nm wavelength is invisible, and the 650nm (red) pointing diode power output is less than 3 mW and spread out over the treatment area. The suggested distance between treatment head and patients' skin is 8 cm.
- Energy source: An adapter (12Vdc, 15A, Max. 180W).

e. Materials of Use

- General type of material used: aluminum and steel
- Duration and type of contact: the laser is set for 10 cycles, of 1 minute and 0 seconds each.

f. Key Performance Specifications/Characteristics of the Device

The CytonPro-5000 has the same wavelength with predicated devices.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The CytonPro-5000 and the aforementioned predicate devices are infrared lamps as defined in 21 CFR890.5500. These devices use infrared laser diodes to generate topical heating for temporary relief of muscle and joint pain. The overall safety and effectiveness of the CytonPro-5000 is not affected by differences in design from the predicate devices.

Performance Characteristic	CytonPro-5000	Cell Gen CG-4000
510(k) Number	Not assigned	K080084
Indications for Use	The model CytonPro-5000 laser emits energy in the infrared spectrum to provide topical heating to elevate tissue temperature for temporary relief of muscle and joint pain, muscle spasm and stiffness associated with arthritis. It also increases blood circulation and relaxes	The model CG-4000 Cell Gen laser emits energy in the infrared spectrum to provide topical heating to elevate tissue temperature for temporary relief of muscle and joint pain, muscle spasm and stiffness associated with arthritis. It also increases blood circulation and relaxes

	muscle tissue	muscle tissue.
Wavelength	1064nm	1064nm
Spectral Width	+/-5nm	+/- 5 nm
Beam Size	50mm	40mm +/- 5mm
Max Output Power from Treatment head	20W	20W
Max Power	800mW/ cm^2	1.6 W/ cm^2
Coupling	200um optical fiber	Integrated Fiber
Umbilical Length	6 ft (2 meters)	6 ft (2 meters)
Minimum Bend Radius	3 in. (75mm)	3 in. (75mm)
Expected Lifetime	> 25,000 hrs	>5000 hrs
Max Input Power	180W	650VA
Input Voltage	100-240VAC, 50/60 Hz	120 V, 60Hz 5A
Temperature Range	Device: 20C ~ 50C Skin: 30C ~ 45C	Device:20C~ 50C Skin: 30C ~ 45C
System Weight	4.8kg	14kg (30.86lbs)

The above comparison table indicates that the CytonPro-5000 is substantially equivalent to the predicate device. In addition, CytonPro-5000 passed all the electrical and safety testing according to national and international testing standards.

The wavelength of the CytonPro-5000 is exactly the same as the predicate device. The input voltage ranges from 100~240v, same as the predicate devices as well.

The max output power of the treatment head is the same as the predicate device Cell Gen CG-4000. The max power density of the CytonPro-5000 is 800mW/cm^2, less than the CG-4000, due to the slightly wider aperture of CytonPro-5000. This advanced lens design produces more evenly distributed and lower peak power density at the center.

The consumed power of the CytonPro-5000 is far less than the prior predicate device, and the weight is much lighter as well.

From the above side-by-side comparison, obviously the CytonPro-5000 is substantially equivalent to the predicate device and safer.

7. PERFORMANCE TESTING (non-clinical)

   Testing of the CytonPro-5000 include Software verification and validation testing, electrical safety testing, and laser testing in accordance with all applicable standards for this type of medical device.

   The following testing of standards were provided in support of the substantial equivalence determination.

   a. Software Verification and Validation Testing

      Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

   b. Electrical Safety Testing

      The CytonPro-5000 device complies with the applicable voluntary standards for Electromagnetic Compatibility and Safety. The device passed all the electrical and safety testing according to national and international standards, as below:

      ANSI/AAMI ES60601-1:2005/A1:2012
      IEC 60601-1-2:2014
      IEC60601-1-6:2010/A1:2013
      IEC 62304:2015
      IEC 60601-2-22
      IEC 60825-1

   c. Temperature Testing

      The CytonPro-5000 induced therapeutic topical heating on the hand and foot of five subjects within 100 seconds for the 800mW/cm2 setting, and within four minutes for the 300mW/cm2 power density setting. Afterwards, the temperature of this therapeutic heating level is kept and slightly increases during this treatment protocol. However, the skin temperature is under very well controlled.

8. CONCLUSION

   In Consideration of the testing and comparison to the predicate device, the CytonPro-5000 has similar function, performance, energy source and intended use to the predicate device. This laser is designed to comply with the generally accepted therapeutic heat performance specifications by producing a level of tissue temperature reported in literature. Therefore, the CytonPro-5000 is substantially equivalent to the Cell Gen CG-4000.