THERALIGHT

TheraLight Regulatory Status Report Fiscal Year 2021

COMPANY: TheraLight, LLC

FOOD & DRUG ADMINISTRATION (FDA U.S.)

The United States Food and Drug Administration is a federal agency of the Department of Health and Human Services.

COMPANY

FDA Company Registration:	Current Certificate Available
Registration Number:	3015152461 TheraLight
Status:	Current
Date of Registration Status:	FY2021
FDA FEI Number:	3015152461 TheraLight FDA Establishment Identification Number (FEI). The FDA uses to track inspections of the regulated establishment or facility
FDA 21 CFR 820 (CGMP) Good Manufacturing Practices:	TheraLight currently meets all FDA CGMP Guidelines
MDUFA Small Business Qualification:	SBD218887 TheraLight - FY2021 Medical Device User Fee Amendments (MDUFA). Small Business Qualification and Certification
North American Industry Classification System (NAICS)	334510 Electromedical and Electrotherapeutic Apparatus Manufacturing
Dun & Bradstreet D-U-N-S Number:	117135001 TheraLight

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (FDA CDRH)

The Center for Device Regulation, Radiation Health, and Research (CDRRHR) is the national agency under the Food and Drug Administration of the Department of Health that regulates the production, import, export, distribution, sale, promotion, and use of electrical/electronic devices capable of emitting radiation

FDA Form FDA-2877:	Current Form Available Declaration for Imported Electronic Products Subject to Radiation Control Standards Form

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PRODUCTS

FDA Products Registration

Status	Current
Date of Registration Status:	FY2021
Trade / Device Name	TheraLight 360 Full Body Wellness Low Level Light Therapy LED Pod TheraLight FIT Full Body Wellness Low Level Light Therapy LED Pod
Device Listing Number	D332854
Product Type	Single Device Product
Regulation Number	21 CFR 890.5500
Regulation Name	Infrared Lamp
Regulatory Class	Class II Device
Product Code	ILY – exempt status – see below
Regulation Medical Specialty	Physical Medicine
Intended Use	The TheraLight Series is intended to emit energy in the visible and IR spectrum intended to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain or muscle spasm, the temporary increase in local blood circulation, and the temporary relaxation of muscles.
FDA 510 k (Clearance)	US Federal Register 2017 Ruling for Exempt Status for Product Code ILY
Global Medical Device (GMD) Number	45688
GMD Description	Phototherapy unit, red light, line-powered
Intended Purpose	This is a device that emits low-level narrow band red light that is intended to be used to modify cellular metabolism to improve tissue repair, reduces pain and inflammation. (i.e., neck pain, oral mucositis, tendinopathies, chronic joint disorders)

INTERNATIONAL

Certificate of Conformity (COC):	International Use: Specific Country COC Available Current Form available for exporters or importers to show that the good or services bought or supplied meet the required standards
Harmonized System (HS) Codes:	HS Code 9018.20.00 Ultraviolet or infrared ray apparatus, and parts and accessories thereof HS Code 9018.20.00.40 Therapeutic

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QUALITY MANAGEMENT SYSTEMS

International Organization for Standardization (ISO)

ISO	Quality Management Systems And Requirements For Regulatory Purposes
ISO 13485	TheraLight currently meets ISO 13485 Certification Standards for Medical Devices

International Electrotechnical Commission (IEC) Standards

IEC	International Standards Organization That Prepares And Publishes International Standards For All Electrical, Electronic, And Related Technologies
IEC 60601–1	TheraLight currently meets IEC Standards Medical electrical equipment. General requirements for basic safety and essential performance
IEC 60601–1–2	TheraLight currently meets IEC Standards Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard; Electromagnetic compatibility; requirements and tests
IEC 60601–1–6	TheraLight currently meets IEC Standards Medical electrical equipment. General requirements for basic safety and essential performance
IEC 60601–2–57	TheraLight currently meets IEC Standards Medical electrical equipment. Requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
IEC60825-1	TheraLight currently meets IEC Standards Safety of laser products - Part 1: Equipment classification and requirements
IEC 62304	TheraLight currently meets IEC Standards Medical device software. Software life-cycle processes
IEC 62366	TheraLight currently meets IEC Standards Medical devices. Application of usability engineering to medical devices
IEC 62471	TheraLight currently meets IEC Standards Photobiological safety of lamps and lamp systems
PD IEC/TR 60878	TheraLight currently meets IEC Standards Graphical symbols for electrical equipment in medical practice

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BS EN ISO 780	TheraLight currently meets BS IEC Standards International British Standards (BS) Distribution packaging. Graphical symbols for handling and storage of packages
BS EN ISO 13485	TheraLight currently meets BS IEC Standards International British Standards (BS) Medical devices. Quality management systems. Requirements for regulatory purposes
BS EN ISO 10993–1	TheraLight currently meets BS IEC Standards International British Standards (BS) Biological evaluation of medical devices. Evaluation and testing within a risk management process
BS EN ISO 14971	TheraLight currently meets BS IEC Standards International British Standards (BS) Medical devices. Application of risk management to medical devices
BS EN ISO 15223–1	TheraLight currently meets BS IEC Standards International British Standards (BS) Medical devices. Symbols to be used with medical device labels, labelling and information
Restriction of Hazardous Substances Directive (RoHS 1)	TheraLight currently meets EU Standards (European Union) Restriction of use of specific hazardous materials in electrical products

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