



Aspen Laser Regulatory Status Report Fiscal Year 2021

COMPANY: Aspen Laser Systems, 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: 3011387816 Aspen Laser

Status: Current

Date of Registration Status: FY2021

FDA FEI Number: 3011387816 Aspen Laser
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: Aspen Laser currently meets all FDA CGMP Guidelines

MDUFA Small Business

Qualification: SBD217248 Aspen Laser - 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: 065949101 Aspen Laser

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 Accession Number: 1420708-000 Aspen Laser
FDA's CDRH assigns number to track reports from specific models of radiation-emitting electronic devices (RED)

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

ASPEN LASER

PRODUCTS

FDA Products Registration

Status Current
Date of Registration Status: FY2021

FDA 510 k Clearances:

510(K) Number K142078 Aspen Laser
Regulation Number 21 CFR Part 890.5500
Regulatory Class Class II Medical Device, Class IV Laser (CDRH)
Classification Product Code ILY
Regulation Medical Specialty Physical Medicine
Clearance Indications for Use Therapeutic

The Aspen Laser System is intended to emit energy in the visible and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis pain, promoting relation of muscle tissue, and to temporarily increase local blood circulation.

510(K) Number K150138 Aspen Laser
Regulation Number 21 CFR Part 878.4810
Regulatory Class Class II Medical Device, Class IV Laser (CDRH)
Classification Product Code GEX, PDZ
Regulation Medical Specialty General & Plastic Surgery
Clearance Indications for Use Podiatry

The Aspen Laser System is cleared for podiatry incision, excision, ablation, vaporization, and coagulation including matrixectomy, periungual and subungual, warts, neuromas, and planter warts. Additional clearance for the temporary increase of clear nail in patients with Onychomycosis (e.g., dermatophytes Trichophyton rubrum and T mentagrophytes, and/or yeasts Candida albicans, etc.).

INTERNATIONAL

Certificate of Conformity (COC): International Use: Specific Country COC Available
Given to 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

QUALITY MANAGEMENT SYSTEMS

International Organization for Standardization (ISO)

ISO Quality Management Systems And Requirements For Regulatory Purposes
ISO 13485 Aspen Laser 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	Aspen Laser currently meets IEC Standards Medical electrical equipment. General requirements for basic safety and essential performance
IEC 60601-1-2	Aspen Laser 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	Aspen Laser currently meets IEC Standards Medical electrical equipment. General requirements for basic safety and essential performance
IEC 60601-2-57	Aspen Laser 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	Aspen Laser currently meets IEC Standards Safety of laser products - Part 1: Equipment classification and requirements
IEC 62304	Aspen Laser currently meets IEC Standards Medical device software. Software life-cycle processes
IEC 62366	Aspen Laser currently meets IEC Standards Medical devices. Application of usability engineering to medical devices
IEC 62471	Aspen Laser currently meets IEC Standards Photobiological safety of lamps and lamp systems
PD IEC/TR 60878	Aspen Laser currently meets IEC Standards Graphical symbols for electrical equipment in medical practice
BS EN ISO 780	Aspen Laser currently meets BS IEC Standards International British Standards (BS) Distribution packaging. Graphical symbols for handling and storage of packages
BS EN ISO 13485	Aspen Laser currently meets BS IEC Standards International British Standards (BS) Medical devices. Quality management systems. Requirements for regulatory purposes

ASPEN LASER

BS EN ISO 10993-1

Aspen Laser 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

Aspen Laser currently meets BS IEC Standards
International British Standards (BS)
Medical devices. Application of risk management to medical devices

BS EN ISO 15223-1

Aspen Laser 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)**

Aspen Laser currently meets EU Standards (European Union)
Restriction of use of specific hazardous materials in electrical products