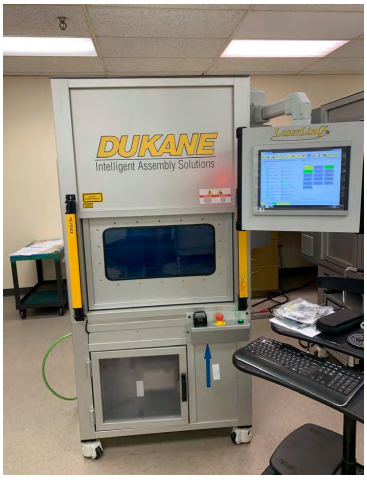
2020 Dukane LW125X300Y300 Laser Welder / Marker

Serial US343216 • 125 W @ 980 nm • FDA Class I • **Zero operating hours since factory service**



Production capability in a development-cell footprint. Dukane specified this system to put the capability of their larger production machines into a cabinet that fits a tight cleanroom — 47 × 57 × 78 in, self-contained, Class I enclosed, on levelling casters. No light-tight room, external chiller, or three-phase service required.

IFOV coordinated motion. Dukane's Infinite Field of View package drives the Raylase galvo and the X-Y servo gantry as one coordinated system rather than indexing between static galvo fields, so weld and mark geometry is not constrained to a single scan-field position. Dukane describes this as a special option, not a standard LW-series feature.

One of only two ever built. Confirmed with the Dukane factory, May 2026.

Provenance

Purchased new November 2019 under Dukane PO 534685. Approximately two years of light production use (Q3 2020 – September 2022), then idled. Third-party calibration February 2023. Full Dukane factory preventative-maintenance service 25 April 2023 — the technicians recorded that the machine *runs and cycles fine*; the report is on file. **The machine was not run again after that service.** The original owner confirmed this in writing at transfer. It moved to the current owner in November 2024 and has remained on its Dukane factory shipping pallet, wrapped and strapped, stored indoors. **Zero operating hours since the factory service.**

Specifications

Manufacturer	Dukane Intelligent Assembly Solutions, St. Charles, IL
Model	LW125X300Y300 (nameplate LW1B125XY300S20L1)
Serial / Build year	US343216 / 2020
Laser source	Sakar SS-125-980-10-200-5-SMA-RA1, S/N 3089 — fiber-coupled diode
Rated power	125 W
Wavelength	980 nm, CW / modulated
Beam delivery	SMA fiber to Raylase Miniscan II-20 galvo; F-theta lens f = 254 mm, coated 940–980 nm
Motion	X-Y servo gantry with Dukane IFOV (Infinite Field of View) coordinated-motion package
Working field	12 in × 12 in (300 mm × 300 mm)
Control	LaserLinQ Windows HMI — recipes, weld preview, alignment, diagnostics, cycle-data logging
Interfaces	Analog 0–10 V; Sub-D 25 I/O (enable / error / ready / pilot / gate); RS-232; Ethernet
Clamping	Pneumatic dual part clamps, FESTO ADNGF-50-15-P-A; integrated vision camera
Safety	Dual Keyence light curtains, dual palm switches, interlocked doors, key control, E-stops in series
Classification	FDA Class I laser product (Class IV embedded, certified Class I final)
FDA accession	2021014-000 — CDRH product code 95R-FF, September 2020 (letter attached, page 3)
Electrical	240 VAC, 25 A, 2Ph+PE, 50/60 Hz
Pneumatic	Clean, dry, unlubricated air, 70–100 PSI
Cooling	Air cooled
Dimensions / weight	47 in W × 57 in D × 78 in H; approx. 2,500 lbs including tooling
Mobility	Levelling feet / casters; pallet-jack or forklift movable

Condition and disclosures

Sold **as-is, where-is**, no warranty expressed or implied. The machine is currently wrapped and strapped on its shipping pallet and is not set up for demonstration; a pre-purchase inspection can be arranged through Dukane factory service (approx. $4,000 site visit plus time and materials) at the buyer's cost. The April 2023 service report notes two open items raised by the operator: an intermittent gantry-drift observation that Dukane deferred for live diagnosis and never characterized, and silicone clamp tooling flagged as old and difficult to work with (a consumable, nominal replacement cost). A Dukane representative indicated informally in May 2026 that gantry drift is not something they see on this platform, though that was a recollection rather than a formal engineering assessment. Laser output power was not re-measured at the 2023 service due to an interlock limitation noted in the report.

Documentation conveyed with the machine

Dukane system manual; electrical schematic and BOM; pneumatics schematic and BOM; mechanical BOM; Sakar laser module manual; Raylase Miniscan II-20 manual; FESTO repair instructions. Compliance package: FDA accession acknowledgment letter 2021014-000; Class I Certification Report and hazard analysis (Laser Safety Compliance LLC); FDA Form 3632 submission with appendices; TRANSCAT third-party calibration certificate (February 2023); Dukane Equipment Maintenance and Status Report (25 April 2023). Clamp tooling and acrylic/silicone fixtures as originally supplied.

Applications

Medical device assembly (implantable housings, microfluidic chip seals, hermetic seals), thin-metal welding, plastic laser-transmission welding, and laser marking — welder and marker in one cell.

Price and terms

As listed. FOB San Diego, California; buyer arranges freight. Price excludes applicable taxes. Sold as-is, where-is, subject to prior sale. Buyer welcome to commission a paid pre-purchase inspection.

Alex Nemiroski, CEO — BioNexus Labs | alex@bionexus.consulting | San Diego, CA

Full documentation package, including the Dukane factory service report and complete certification file, available to qualified buyers on request. Attached: FDA Center for Devices and Radiological Health acknowledgment letter assigning accession number 2021014-000 to this model and serial number.

U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 25, 2020

Sergio F Cordova
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Reference: 2021014-000

This is to acknowledge receipt of your June 15, 2020, document, which was filed pursuant to the regulations for the administration and enforcement of the Radiation Control for Health and Safety Act of 1968 (title 21, code of Federal Regulations, Subchapter J) as they pertain to Product Report requirements.

Your document has been assigned an Accession Number of 2021014-000, and has been classified as a(n) Product Report (pursuant to Part 1002, Subpart B of the Regulation referenced above).

Further, the submittal has been assigned an informal subject title of "This submission is a(n) Product Report. These Material Processing Laser Products: For the Dukane Model LW1B125XY300S20L1 Serial Number 343216. (Mfg. by Dukane Intelligent Assembly Solutions)."

This acknowledgement does not constitute approval of the document. You will be contacted if any questions or comments arise concerning your document.

WARNING:

THE ACCESSION NUMBER ASSIGNED TO YOUR SUBMISSION DOES NOT IMPLY, CONVEY OR CONSTITUTE FDA APPROVAL OF ANY REPORT, APPLICATION FOR VARIANCE OR EXEMPTION, NOTIFICATION, OR ANY OTHER SUBMISSION OR ITS CONTENTS. THE ACCESSION NUMBER IS ONLY AN ACKNOWLEDGMENT THAT FDA HAS RECEIVED YOUR SUBMISSION. IT MAY BE REVOKED BY FDA. ITS DISCLOSURE IS YOUR RESPONSIBILITY. IT IDENTIFIES YOUR SUBMISSION FOR PRODUCTS OR PRODUCT FAMILIES IDENTIFIED IN THIS MESSAGE.

Be advised that failure to comply with FDA regulations may result in notification of affected persons and corrective actions at no cost to the purchaser, pursuant to 21 CFR Part 1003 -- Discovery of Defect or Failure to Comply and 21 CFR Part 1004 -- Repurchase, Repairs, or Replacement of Electronic Products.

Please be aware that the following CDRH Product Code(s) have been assigned to the product(s) described in this report:

RFF defined as Laser Welder

If these products will be shipped to the United States, the shipping broker will need to provide the full FDA Product Code at the time of entry, structured as follows:

95R- -FF

Please note that your firm is required to submit an Annual Report to CDRH every year by September 1.

All Radiological Reports may be prepared using FDA's Electronic Submissions software which can be downloaded at http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm108165.htm. For more information on the FDA's eSubmitter program please see the following websites:

Radiological Health - http://www.fda.gov/Radiation-EmittingProducts/default.htm

Electronic Submissions (instead of paper reports) - http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm

FDA Electronic Submissions Gateway - http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm

If you have any questions, please contact the Director of the Division of Radiological Health, or the branch chief of your respective product area, as listed on the CDRH Management Directory, under the Office of In Vitro Diagnostics and Radiological Health, Division of Radiological Health. http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm127854.htm

Please include a primary (and optional secondary) contact email address in all submissions (and/or cover letters) to facilitate electronic correspondence.

Sincerely yours,

Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health