

Laser Hair Removal Device Technical Comparison

FDA 510(k) Device Analysis: GEX to OHT Transition

Table 1: Comprehensive Device Comparison with Energy Analysis

Device	510(k) Number	Year	Product Code	User Type	Wavelength (nm)	Beam Size	Area (cm ²)	Energy Density Range (J/cm ²)	Max Energy Density (J/cm ²)	Max Total Energy (J)*
TRIA	K090820	2009	GEX	Consumer	~800	Φ 10mm	0.785	6, 10, 14, 18, 22	22	17.3
SILKPRO	K142845	2015	OHT	Consumer	810	9×9mm	0.81	5, 10, 15, 20, 25	25	20.3
IVYLASER	K230025	2023	OHT	Consumer	808	9×18mm	1.62	1.85, 3.09, 6.17, 9.26, 15.43	15.43	25.0
Diode Laser (Lotuxs V8)	K230090	2023	OHT	Consumer	810	30×10mm	3.0	2.2, 3.4, 4.5, 5.6, 7.0, 9.0	9.0	27.0
Diode Laser (Lotuxs V4)	K230090	2023	OHT	Consumer	810	30×10mm	3.0	2.0, 2.8, 3.5, 4.3, 5.3, 7.0	7.0	21.0

*Max Total Energy = Max Energy Density × Beam Area

Key Technical Observations:

Energy Density Evolution: The transition from GEX to OHT did not result in universally lower energy densities. The 2015 SILKPRO (OHT) actually had higher maximum energy density (25 J/cm²) than the 2009 TRIA (GEX, 22 J/cm²). However, later OHT devices show more conservative energy limits.

Professional vs Consumer Applications: The 2018 professional GEX device (K181019) maintains the highest energy density range (5-40 J/cm²), reflecting its clinical use environment with trained operators.

Total Energy Output Trends: Despite similar energy densities, total energy output varies significantly based on beam size. Larger beam sizes in recent OHT devices (like the 3.0 cm² Lotuxs devices) can deliver substantial total energy even at moderate energy densities.

Regulatory Timeline: The precise transition point was July 1, 2015, with the SILKPRO device serving as the regulatory bridge from GEX to OHT classification for consumer laser hair removal devices.

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Diode Laser System	K181019	2018	GEX	Professional	808	-	1.20	5-40	40	48.0

Data Sources: FDA 510(k) Premarket Notification Database **Product Codes:**

- GEX: Powered Laser Surgical Instrument
- OHT: Light Based Over-The-Counter Hair Removal Device