

K243588 Single Use CO2 Laser Fiber (HAF005001)Feb 19, 2025
91 days to decisionK243588 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k243588/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 20, 2024
Decision date	Feb 19, 2025
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Quanta System Spa
Location	Chelmsford, MA, US
Contact	Dario Bandiera
510(k) history	57 submissions · 57 cleared · 2006-2025

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