

K160368 EVO platformApr 5, 2016
56 days to decisionK160368 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k160368/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 9, 2016
Decision date	Apr 5, 2016
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Quanta System Spa
Location	Chelmsford, MA, US
Contact	FRANCESCO DELL'ANTONIO
510(k) history	57 submissions · 57 cleared · 2006-2025

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