

K192160 EVO PlatformSep 6, 2019
28 days to decisionK192160 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k192160/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 9, 2019
Decision date	Sep 6, 2019
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

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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