

K211228 RossoFeb 2, 2022
285 days to decisionK211228 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k211228/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 23, 2021
Decision date	Feb 2, 2022
Days to decision	285 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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