

K180922 Empower H100, Cyber Ho 100, Litho 100May 8, 2018
29 days to decisionK180922 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k180922/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 9, 2018
Decision date	May 8, 2018
Days to decision	29 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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