

K180423 Empower H65Mar 15, 2018
27 days to decisionK180423 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k180423/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 16, 2018
Decision date	Mar 15, 2018
Days to decision	27 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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