

K201111 GentleMax Pro PlusMay 26, 2020
29 days to decisionK201111 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k201111/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 27, 2020
Decision date	May 26, 2020
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Candela Corporation
Location	Wayland, MA, US
Contact	Yverre Bobay
510(k) history	8 submissions · 8 cleared · 2015-2024

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