

K190007 Vydenze Laser FamilyMar 1, 2019
58 days to decisionK190007 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k190007/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 2, 2019
Decision date	Mar 1, 2019
Days to decision	58 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Vydenze Medical Industria E Comercio Ltda
Location	Ceat - Sao Carlos/Sp Sao Paulo, BR
Contact	Kathy Maynor
510(k) history	4 submissions · 4 cleared · 2018-2022

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