

K171443 Etherea MXApr 20, 2018
339 days to decisionK171443 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k171443/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 16, 2017
Decision date	Apr 20, 2018
Days to decision	339 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Vydence 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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