

K202998 Vydenze Zye and Vydenze OneOct 26, 2021
390 days to decisionK202998 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k202998/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 1, 2020
Decision date	Oct 26, 2021
Days to decision	390 days
Third-party review	No
Combination product	No
PCCP authorized	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

REGULATORY CONSULTANT

Consulting firm	Kathy Maynor
Contact	Kathy Maynor

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202998/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026