

K200736 Stardust MedJun 26, 2020
95 days to decisionK200736 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k200736/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 23, 2020
Decision date	Jun 26, 2020
Days to decision	95 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	I.T.S. Group S.R.L.
Location	Calderara Di Reno, IT
Contact	Claudio Bellina
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Endo Engineering S.R.L.
Contact	Chiara Violini

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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